IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* AMY BERGMAN; the DISTRICT of COLUMBIA *ex rel.* AMY BERGMAN, CALIFORNIA *ex rel.* AMY BERGMAN, DELAWARE *ex rel.* AMY BERGMAN, FLORIDA *ex rel.* AMY BERGMAN, GEORGIA *ex rel.* AMY BERGMAN, HAWAII *ex rel.* AMY BERGMAN, ILLINOIS *ex rel.* AMY BERGMAN, INDIANA *ex rel.* AMY BERGMAN, LOUISIANA *ex rel.* AMY BERGMAN, MASSACHUSETTS *ex rel.* AMY BERGMAN, MICHIGAN *ex rel.* AMY BERGMAN, MONTANA *ex rel.* AMY BERGMAN, NEVADA *ex rel.* AMY BERGMAN, NEW HAMPSHIRE *ex rel.* AMY BERGMAN, NEW JERSEY *ex rel.* AMY BERGMAN, NEW MEXICO *ex rel.* AMY BERGMAN, NEW YORK *ex rel.* AMY BERGMAN, OKLAHOMA *ex rel.* AMY BERGMAN, RHODE ISLAND *ex rel.* AMY BERGMAN, TENNESSEE *ex rel.* AMY BERGMAN, TEXAS *ex rel.* AMY BERGMAN, VIRGINIA *ex rel.* AMY BERGMAN, WISCONSIN *ex rel.* AMY BERGMAN, and AMY BERGMAN, individually, Plaintiffs, v. ABBOTT LABORATORIES, Defendant.	:	CIVIL ACTION NO. CV09-4264-JONES JURY TRIAL DEMANDED

AMENDED COMPLAINT

1. Plaintiff-Relator Amy Bergman brings this civil action for the United States of America (Government or United States), the states the states of Illinois, California, Delaware,

District of Columbia, Florida, Georgia, Hawaii, Louisiana, Massachusetts, Montana, Tennessee, Texas, Virginia, Indiana, Nevada, New Hampshire, New Mexico, Michigan. New York, Oklahoma, Wisconsin. Rhode Island, New Jersey, and for herself and against Abbott Laboratories ("Abbott").

2. This is an action to recover damages and civil penalties on behalf of the United States and the Plaintiff-Relator arising from false and/or fraudulent statements and claims made, used and caused to be made used or presented by Defendant Abbott and/or its agents and employees in violation of the Federal False Claims Act, 31 U.S.C. §§ 3729 *et seq.* and the false claims acts of various states, specifically, In favor of Plaintiff-Relator Bergman for the maximum amount allowed as Relator's share pursuant to the Plaintiff State FCAs as follows: the Illinois False Claims Act, 740 ILCS 175, *et seq.*; the California False Claims Act, Cal. Gov. Code §§12650, *et seq.*; the Delaware False Claims and Reporting Act, 6 Del. C. §§1201, *et seq.*; the District of Columbia False Claims Act, D.C. Code §§2-308.14, *et seq.*; the Florida False Claims Act, Fla. Stat. §§68.081, *et seq.*; Georgia State False Medicaid Claims Act, Ga. Code §§49-4-168, *et seq.*; the Hawaii False Claims Act, False Claims to the State, HRS §§661-21, *et seq.*; the Louisiana Medical Assistance Programs Integrity Law, La. R.S. §§46:437, *et seq.*; Massachusetts False Claims Act, ALM GL ch.12 §§5A, *et seq.*; the Montana False Claims Act, Mont. Code Anno., §§17-8-401, *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-181, *et seq.*; the Tennessee False Claims Act, Tenn. Code Ann. §§4-18-101, *et seq.*; the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code, §§36.001, *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1, *et seq.*; the Indiana False Claims and Whistleblower Protection Act, Burns Ind. Code Ann. §§5-11-5.5, *et seq.*; the Nevada False Claims Act, Submission of False Claims to State or Local

Government, Nev. Rev. Stat. Ann. §§357.010, *et seq.*; the New Hampshire False Claims Act, §§167:61-b, *et seq.*; the New Mexico False Claims Act, N.M. Stat ANN. §§27-14-1 *et seq.*; New Mexico Fraud Against Taxpayers Act, N.M. Stat. §§44-9-1 *et seq.*; the Michigan Medicaid False Claims Act, MCLS §§400.601, *et seq.*; the New York False Claims Act, NY CLS St Fin, §§187 *et seq.*; Oklahoma Medicaid False Claims Act, 63 Okla. Stat. §§5053, *et seq.*; Wisconsin False Claims for Medical Assistance Act, WIS. STAT. §§20.931, *et seq.*; Rhode Island State False Claims Act, R.I. Gen. Laws §§9-1.1-1, *et seq.*; and the New Jersey False Claims Act, N.J. STAT. §§2A:32C-1. In support thereof, Plaintiff-Relator Amy Bergman states and avers as follows:

I. INTRODUCTION

3. This action concerns the improper and illicit off-label marketing of the billion dollar a year prescription drug TriCor, violations of the Medicare and Medicaid Anti-Kickback Statute, 42 U.S.C. §1320a-7b, and other illegal activities described below, by Abbott relating to the marketing of TriCor, which directly caused and resulted in the submission of many thousands of false claims for reimbursement to be made to the United States and to the States.

4. TriCor (generic name fenofribate) is a lipid-regulating agent that was approved by the FDA as an "adjunctive therapy to diet" for treatment of adult patients with certain types of hypercholesterolemia, mixed dyslipedemia, or hypertrigliceridemia. With respect to efficacy, however, the Food and Drug Administration (FDA) specifically found that the effect of TriCor on "coronary heart disease morbidity and mortality and non-cardiovascular mortality has not been established." TriCor was *not* approved by the FDA as a first-line treatment for diabetic patients. TriCor was also *not* approved by the FDA for use in combination with statin drugs.

5. In order to expand its sales of TriCor, and placing the pursuit of profits ahead of patient safety and the law, Abbott engaged in an illegal nationwide, coordinated and deceptive

scheme of false and misleading promotion and marketing of TriCor. Abbott's illegal marketing scheme was multi-faceted, and was executed with the knowledge, direction and encouragement of Abbott and its management.

6. Abbott's illicit marketing scheme involved the marketing of TriCor for uses (indications) not approved by the FDA, a practice known in the pharmaceutical industry as "off-label marketing." The off-label uses that Abbott promoted were unsafe and/or ineffective uses for TriCor that, at best, resulted in a waste of patients' and third-party payors' health care expenditures and, at worst, threatened the health and safety of the patients for whom TriCor was prescribed for the off-label and medically unnecessary uses.

7. In order to effectuate its unlawful marketing scheme for TriCor, Abbott improperly promoted TriCor as a first-line treatment for treating or preventing cardiac health risks in diabetic patients even though TriCor was not approved for such use by the FDA and even though TriCor ***had no demonstrated effect*** on cardiovascular morbidity and mortality in the diabetic population. Abbott also improperly promoted TriCor for use in combination with highly popular statin drugs even though TriCor was not approved for use in combination with statins by the FDA, and despite ***specific warnings*** regarding combined use with statins contained in the FDA-mandated product labeling. Abbott also made regular representations concerning the efficacy of TriCor which were contrary to the FDA required labeling, were false and misleading, and which did not represent the FDA required fair balance of information regarding uses and risks.

8. Abbott's illegal marketing scheme for TriCor also involved making unlawful payments and giving other illicit financial incentives to physicians in order to get them to

prescribe TriCor, including for off-label and medically unnecessary uses, in a knowing violation of the Medicare and Medicaid Anti-Kickback statute.

9. Abbott's deceptive and off-label marketing of TriCor resulted in TriCor becoming "misbranded" under the Food, Drug and Cosmetic Act. It was and is a violation of federal law to introduce a misbranded drug into interstate commerce, or to cause a drug in interstate commerce to become misbranded. 21 U.S.C. §331(a) and (b).

10. Generally, no payments may be made under the Medicare and Medicaid programs for expenses incurred for items and services, including drugs, that are not "reasonable and necessary" for the diagnosis and treatment of an illness or injury. See, 42 U.S.C. §1395y(a)(1)(A). Medicare, Medicaid and other government funded health insurance payors, such as TRICARE and the Federal Employee Health Benefits Program, do not cover and pay for off-label uses of prescription drugs, except for in very limited circumstances not applicable here. The off-label uses that were the object of Abbott's illegal marketing scheme were not "reasonable and necessary." The Medicare and Medicaid programs also do not cover or pay for claims for reimbursement that were the result of violations of the Medicare and Medicaid Anti-kickback statute.

11. As a direct result of Abbott's illegal off-label marketing and misbranding of TriCor, physicians prescribed TriCor for off-label uses and/or for uses which were not reasonable and necessary for treatment, and claims for reimbursement for off-label uses and medically unnecessary uses of TriCor were submitted to the federal government and the States in connection with such prescriptions, giving rise to liability under their respective False Claims Acts. The United States and the States would not have paid these claims for TriCor but for Abbott's illegal and fraudulent conduct.

12. Starting no later than 2000, and continuing until at least 2008, and upon information and belief continuing to the present, Abbott management trained, directed, incentivized and encouraged their TriCor sales force to promote TriCor to physicians for off-label and medically unnecessary uses in order to effectuate Abbott's illegal scheme to increase the market for TriCor. During the same time, Abbott also provided its sales and marketing staff, as well as its other divisions, with funds to provide financial incentives to physicians to persuade them to prescribe TriCor instead of other competing drugs, as well to prescribe TriCor for off-label and medically unnecessary uses, in knowing violation of the Medicare and Medicaid Anti-kickback statute.

13. Specifically, Abbott trained, directed, incentivized and encouraged its sales representatives:

a. to market TriCor for uses outside those listed on the FDA-approved label;

b. to misrepresent and withhold clinical information regarding the known risks associated with the use of TriCor, particularly in combination with statins;

c. to misrepresent and withhold clinical information regarding questions concerning the efficacy of TriCor;

d. to misrepresent that TriCor was superior to other drugs when clinical studies either established otherwise, or where there was no clinical study comparing the two drugs; and

e. to improperly use study results of other drugs to suggest that TriCor would have the same or better results.

14. These misrepresentations regarding TriCor were an integral component of Abbott's scheme to illegally increasing sales of TriCor because clinical studies of TriCor did not

support its efficacy and/or safety for the off-label and medically unnecessary uses Abbott instructed its sales representatives promote. In fact, TriCor's legitimate medical use and market share had been limited because TriCor lacked positive outcomes data in the clinical studies of TriCor that did exist. The clinical studies of TriCor failed to establish that TriCor had a meaningful impact in preventing fatal heart attacks, showed minimal impact on other outcomes criteria (in some cases actually showing that TriCor *increased* morbidity and mortality), and showed that TriCor was inferior to its competitor lipid lowering drugs in preventing non-fatal and fatal heart attacks in most patient types.

15. Among the methods that Abbott used to carry out its illegal marketing scheme for TriCor were the following:

a. training sales representatives on the off-label and medically unnecessary uses that Abbott wanted to promote, and instructing sales representatives to promote those uses for TriCor when making sales calls to physicians;

b. providing sales aids and materials to its sales representatives that promoted off-label and medically unnecessary uses of TriCor;

c. providing clinical studies, including studies of other drugs, to its sales representatives that promoted off-label and medically unnecessary uses of TriCor;

d. training sales representatives to promote TriCor for combination therapy with statins, but instructing them to not discuss or minimize the FDA required warning regarding the dangers of combination therapy;

e. instructing sales representatives to not openly document off-label discussions they had with physicians in their sales call notes, and/or instructing them to use a

particular code in their call notes to document, but conceal, that they had promoted off-label uses of TriCor;

f. paying physician speakers to promote off-label and medically unnecessary uses of TriCor at Abbott sponsored dinners and continuing education presentations;

g. training sales representatives to conduct sales presentations in a way that was designed to lead physicians to ask about off-label uses for Tri-Cor that Abbott knew the sales representatives were prohibited from initiating absent such a request;

h. training sales representatives to make favorable product comparisons of TriCor to competing products when no head-to-head study had been conducted comparing the two drugs;

i. providing sales representatives with cards to give to physicians which contained a website address for an Abbott run website that contained materials promoting off-label and medically unnecessary use of TriCor;

j. instructing sales representatives to promote off-label and medically unnecessary use of TriCor by providing them with funds to be used for speaker honoraria, meals, preceptorship honoraria and other benefits to be provided to physicians as a reward for prescribing TriCor for off-label and medically unnecessary uses, to encourage them to write TriCor for off-label and medically unnecessary uses, or based upon their ability to influence other physicians to prescribe TriCor for off-label and medically unnecessary uses.

k. pressuring and incentivizing sales representatives to promote TriCor for off-label and medically unnecessary uses by setting performance goals linked to market expansion; and

l. pressuring and incentivizing sales representatives to promote TriCor for off-label and medically unnecessary uses by linking sales representative's bonuses to market expansion.

16. As a result of Abbott's wrongdoing, patients were put at risk of serious physical harm, and patients and health insurance payors (including the United States and the States) were financially harmed by:

a. the disruption or discontinuation of stable and beneficial treatment regimens that the patients had been on;

b. the risk of serious side effects from the use of TriCor, such as: rhabdomyolysis (the destruction or degeneration of muscle tissue); myopathy; liver damage; kidney damage, gallstones, pancreatitis; thrombocytopenia; interference with other medications; and increased cancer risk, among others;

c. the increased costs associated with treating side effects caused or exacerbated by the use of TriCor; and

d. the increased costs associated with taking TriCor in the case of combination therapy and for other medically unnecessary uses.

17. As Abbott was fully aware, a substantial percentage of TriCor prescriptions to be written for the off-label and/or medically unnecessary uses Abbott was promoting would be and were paid for by Medicare, Medicaid, and other government-funded health insurance programs. As Abbott was fully aware, a significant portion of the patient segment that Abbott was targeting

with its illegal marketing scheme were poor, elderly or disabled, and would be covered by one or more Government health insurance programs such as Medicare and Medicaid.

18. Abbott also knew that a substantial portion of the prescriptions for TriCor which resulted from unlawful remuneration to physicians in violation of the Medicare and Medicaid anti-kickback statute would be borne by Government health programs, including Medicare and Medicaid. This is so because a significant portion of the patient population that Abbott sought to have prescribed TriCor through its illegal payments to physicians were covered by one or more Government-funded health insurance programs.

19. As a consequence of Abbott's illegal marketing scheme, Abbott caused TriCor to be prescribed when it should not have been and substantially increased the market for TriCor, increasing annual sales to well past a billion dollars a year in the United States. Claims for such prescriptions were submitted to and reimbursed by Medicare, Medicaid, and other Government-funded and State-funded health insurance programs. Had the United States and the States known that such prescriptions had been prescribed for off-label and/or medically unnecessary purposes, or had been induced by illicit incentives, they would not have reimbursed claims for this drug. Abbott thereby caused false claims for payment to be submitted to Medicare, Medicaid, and other Government-funded and State-funded health insurance programs. The federal and state false claims acts provide redress for this conduct.

20. An important feature of TriCor that made it so attractive and profitable for Abbott to promote for off-label and medically unnecessary use is that, as a lipid regulating drug, it is typically prescribed for long-term daily use by patients. Thus, once Abbott was able to convince or induce a physician to prescribe TriCor for a patient, Abbott knew that it would realize a steady

stream of illicit profits well into the future. Indeed, Abbott continues to reap the fruits of its unlawful TriCor marketing scheme today to the substantial harm of patients and taxpayers.

21. Relator Amy Bergman became aware of Abbott's unlawful and violative marketing scheme for TriCor as a result of her employment by Abbott as a marketing representative. One of the products Ms. Bergman was assigned to promote was TriCor. Ms. Bergman was specifically trained, directed, incentivized and encouraged by Abbott, as where the other Abbott marketing representatives, to promote TriCor for off-label and medically unnecessary uses, and to target and provide illegal financial incentives to physicians in order to encourage them to prescribe TriCor, including for off-label and medically unnecessary uses. Amy Bergman has personal and direct knowledge of the allegations contained in this Amended Complaint. Relator Amy Bergman brings this False Claims Act *qui tam* action on behalf of the United States and the States to recover damages for the false claims that have been and continue to be submitted as a direct result of Abbott's unlawful actions described in this Amended Complaint.

II. JURISDICTION AND VENUE

22. This is a civil action arising under the laws of the United States to redress violations of 31 U.S.C. §§ 3729 *et seq.* This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 31 U.S.C. § 3732 and 28 U.S.C. § 1345. This Court has supplemental jurisdiction over the counts relating to the State False Claims Acts pursuant to 28 U.S.C. § 1367.

23. Jurisdiction and venue are proper in this judicial district because this is a district in which an act proscribed by 31 U.S.C. § 3729 occurred, and under 31 U.S.C. § 3730(b)(1) because Abbott is qualified to do business in Pennsylvania and transacts business within this district.

24. This action is not based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the United States is already a party.

25. This action is not based upon public disclosure of allegations or transactions in a criminal, civil, or administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media.

26. To the extent there has been a public disclosure unknown to Amy Bergman, Amy Bergman is an original source under 31 U.S.C. § 3730(e)(4). She has direct and independent knowledge of the information upon which the allegations of this Amended Complaint are based and has voluntarily provided the information to the Government before filing this action based on the information.

27. Amy Bergman has provided to the Attorney General and the United States Attorney for the Eastern District of Pennsylvania, a written disclosure of substantially all material evidence and information Bergman possesses.

28. Bergman has provided the required notices and disclosures regarding this action to the States.

III. PARTIES

29. Plaintiff-Relator Amy Bergman (Bergman) resides and is domiciled in Boca Raton, Florida, and is a citizen of the State of Florida.

30. Defendant Abbott Laboratories (Abbott) is a corporation organized under the laws of the State of Illinois with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064, and is a citizen of Illinois. Abbott regularly transacts business in this judicial district.

31. Abbott is engaged in the business of manufacturing and selling pharmaceutica s. and markets and sells pharmaceuticals nationally and internationally. At all times relevant to th is ac tion, Abbott maintained a national sales force organized and supported under the direction of Abbott's national office in Abbott Park, Illinois. According to Abbott's Annual Report (Form 10-K) filed with the United States Securities and Exchange Commission ("SEC") for 2008, Abbott generated gross revenue in excess of $7.9 billion for the fiscal year ending December 31, 2008.

32. According to annual reports filed by Abbott with the SEC from 1998 through at least 2008, TriCor has been one of Abbott's principal products. As a consequence of Abbot 's illegal marketing scheme for TriCor, annual sales of TriCor have increased dramatically in the United States, from approximately $403 million in 2002, to approximately $1.3 billion in 2008, its second highest grossing drug for the year 2008.

33. Abbott's sales and marketing in the United States are organized by geographic areas under the direction of its national sales office. Each area is organized into regions, and each region is organized into districts and marketing territories. Abbott employs sales representatives with responsibilities for certain products within a territory. Sales materials, training and funding are provided by or under the direction of the national office. Abbott's sales representatives receive incentive-based compensation that includes an annual salary plus a bonus based on sales within the relevant market.

34. Abbott began marketing TriCor (fenofibrate) in 1998.

35. From July 1, 1999, through January, 2008, Amy Bergman was employed by Abbott as a sales representative in its southeast area. From January 2000 through January 2008, Bergman was responsible for marketing TriCor in certain territories in Florida. Bergman

received training and sales materials from Abbott and she attended quarterly training sessions run by representatives of Abbott's national sales office. Bergman was the lead TriCor sales representative in her region. Bergman is personally familiar with Abbott's marketing campaign for TriCor, including Abbott's illegal marketing scheme for TriCor, and the manner in which the marketing strategies for TriCor were implemented.

IV. DRUG APPROVAL AND MARKETING RESTRICTIONS

36. The pharmaceutical industry is highly regulated by the Food and Drug Administration (FDA), and is subject to the requirements of the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (FDCA), and the regulations promulgated by the FDA.

37. Under the FDCA, pharmaceutical drugs may not be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a) and (d). Approval of a drug by the FDA for marketing is the final stage of a multi-year process of study, testing and evaluation.

38. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved by the FDA for treatment of a specific condition for which the drug has been tested in patients and established through significant clinical studies to be both safe and effective. The specific approved use is called the "indication" for which the drug may be prescribed. The FDA will also specify particular dosages determined to be safe and effective for each indication.

39. The indications and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also reviewed and approved by the FDA. 21 U.S.C. §§352, 355(d). A drug's labeling includes the printed insert in the drug's packaging (package insert). The FDA will only approve a new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. §355(d).

40. Under the Food and Drug Administration Modernization Act of 1997 (FDAMA), if a manufacturer wishes to market or promote an approved drug for an alternative use, *i.e.*, uses not listed on the approved package insert, the manufacturer must resubmit the drug for another series of clinical trials similar to those for the initial approval. 21 U.S.C. §360aaa(b) & (c). Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label." "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's approved labeling. Off-label use includes treating a condition not indicated in the drug's package insert, treating the indicated condition at a different dose or frequency than specified in the drug's package insert, or treating a different patient population (e.g., treating a child when the drug is approved to treat adults).

41. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit doctors from prescribing the drug for uses that are different from those approved by the FDA.

42. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. Specifically, under the Food, Drug and Cosmetic Act: 1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and 2) a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§331, 352.

43. An off-label use of a drug can cease to be off-label only if the manufacturer submits a supplemental application and demonstrates to the satisfaction of the FDA "that the product is safe and effective for the proposed new use." 21 U.S.C. §360aaa (b)&(c).

44. In addition to prohibiting manufacturers from directly marketing and promoting a drug's off-label uses, Congress and the FDA have enacted laws and regulations intended to prevent manufacturers from employing indirect methods to accomplish the same improper end. For example, Congress and the FDA have attempted to regulate two of the most prevalent indirect promotional strategies: 1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of its products, and 2) manufacturer support for Continuing Medical Education (CME) programs that focus on off-label uses. With regard to the first practice — disseminating written information — the FDAMA only permits a manufacturer to disseminate information regarding off-label usage in response to an "unsolicited request from a health care practitioner." 21 U.S.C. §360aaa-6 (emphasis added). In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted an application to the FDA seeking approval of the drug for the off-label use; has provided the materials to the FDA prior to dissemination; and the materials themselves must be in an unabridged form and must not be false or misleading. 21 U.S.C. §§360aaa (b)&(c); 360aaa-1.

45. Pursuant to provisions in the FDCA, the FDA strictly regulates the content of consumer and physician-based advertising, direct-to-physician product promotion, and drug labeling information used by pharmaceutical companies in promoting and selling FDA approved prescription drugs.

46. Under 21 C.F.R. § 202.1(k)(2), any brochures, handouts, slide shows or other such promotional materials aimed at physicians are deemed to be "product labeling" which is regulated as such.

47. Under relevant FDA regulations, product labeling must be pre-approved by the FDA and conform to very exacting requirements concerning, among other things, drug interactions, warnings, indicated uses and claims concerning efficacy of a drug or its superiority over competing products.

48. All claims made in any labeling material must be truthful, not misleading, and represent a fair balance of the information about drug risks as compared with information about drug benefits.

49. Any failure to fairly and accurately represent the required information about a prescription drug is considered misbranding and is a false and fraudulent statement as a matter of law. See, 21 U.S.C. §§ 331(a) and (b), 352(a), (f) and (n); 21 C.F.R. § 201.57.

50. Pharmaceutical promotional and marketing materials and presentations lacking in fair balance or that are otherwise false or misleading violate the FDCA, and regulations promulgated thereunder. Such violations exist where promotional and marketing materials and presentations for an FDA approved drug:

(a) Minimize, understate or misrepresent the risks, contraindications and complications associated with that drug;

(b) Promote off label indications of the drug which were not FDA-approved indications, or expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated;

(c) Make comparative claims about the drug that have not been demonstrated by substantial evidence, such as comparative clinical studies with competing drugs and/or drug indications of patient usage, warnings and safety claims including side effects, physician preference, or

(d) Are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketed or any competing drug.

51. With regard to manufacturer involvement in CME programs, the FDA's examination of these practices led to publication of an agency enforcement policy in 1997 entitled, "Guidance for Industry: Industry-Supported Scientific and Educational Activities," 62 Fed. Reg. 64,074, 64,093, 1997 WL 740420 (F.R.) (1997). This guidance document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." *Id.* These factors include, among others, an examination of the relationship between the program provider and supporting company, the company's control of content and selection of presenters, whether there is a meaningful disclosure of the company's funding and role in the program, whether multiple presentations of the same program are held, whether the audience is selected by the sales and marketing department of the company, and whether information about the supporting company's product is disseminated after the initial program other than in response to an unsolicited request. *Id.* The promotion of off-label drug uses at a CME program which fails this test of "independence" violates off-label marketing restrictions.

52. In sum, the off-label regulatory scheme protects patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body, the FDA.

V. TRICOR AND ABBOTT'S ILLEGAL MARKETING SCHEME FOR TRICOR

A. BACKGROUND AND PLAN

53. The FDA has approved TriCor for the treatment of specific medical conditions accompanied by certain warnings and restrictions. The FDA also has approved a specific package insert for TriCor. The TriCor package insert is attached hereto and incorporated by reference as Exhibit 1.

54. When Abbott began marketing TriCor in 1998, Abbott had hoped to find a substantial market for TriCor, and to that end Abbott heavily promoted TriCor through its in-house sales force and by other means. Despite initial efforts at legitimate promotion of TriCor, Abbott was only able to capture a small percentage of the lipid regulating drug market with TriCor. This was so because TriCor lacked meaningful positive outcomes data in the clinical studies done with TriCor, and because many of its competitor lipid regulating drugs (principally statins), had become the drug of choice for most physicians. The reason the competitor medications were the drug of choice of so many physicians was because these other drugs had significant clinical trial data supporting their efficacy in reducing cardiovascular morbidity and mortality, whereas TriCor did not.

55. Abbott, seeking to bolster it revenues from the sale of TriCor, launched an illicit marketing scheme intended to increase sales, including to Government-funded health insurance programs, through the promotion of off-label and medically unnecessary uses for TriCor. Abbott's illegal marketing scheme for TriCor involved inducing physicians to prescribe TriCor for such uses through false, misleading and illegal off-label promotion of TriCor, and through illegal remuneration to physicians. The natural, intended and foreseeable effect of such unlawful

conduct was claims for payment being submitted to Government-funded health plans that were ineligible for reimbursement pursuant to these programs' requirements and regulations.

B. TriCor's Approved Indications

56. TriCor is described in the Package Insert as a "lipid regulating agent."

57. TriCor is indicated as an adjunctive therapy to diet for treatment of adult patients with certain types of hypercholesterolemia, mixed dyslipedemia, or hypertriglyceridemia.

58. With regard to the efficacy of TriCor in producing positive cardiovascular outcomes, the Package Insert states: "The effect of TriCor on cardiovascular morbidity and mortality and non-cardiovascular mortality has not been established."

59. TriCor is *not* approved or indicated as a first-line drug for treatment for diabetic patients.

60. TriCor is *not* approved or indicated for combination therapy with statin drugs.

61. With regard to the use of TriCor in combination with statins, the Package Insert contains specific warnings. Under the heading "WARNINGS," the Product Insert states: "The combined use of TriCor and HMG-CoA reductase inhibitors [statins] should be avoided unless the benefit of further alterations in lipid levels is likely to outweigh the increased risk of this drug combination."

62. The Package Insert further indicates that such combination uses of fibric acid derivatives [such as TriCor] and statins are associated with rhabdomyolysis, markedly elevated creatine kinase levels and myoglobinuria, leading in a high proportion of cases to acute renal failure.

C. Off Label Promotion of TriCor as a First-Line Treatment for Patients with Diabetes

63. Diabetes is a significant health problem in the United States, with an increasing number of patients in the United States being diagnosed and treated for the disease. One complication of diabetes that diabetic patients face is heart disease, with a significant number of diabetics experiencing heart attacks, even those with normal or only slightly abnormal cholesterol levels. Because of an apparent increased risk of heart disease from diabetes, the American Diabetes Association recommended that diabetics, even those without evidence of heart disease or significantly abnormal cholesterol levels, be prescribed lipid lowering drugs.

64. As a consequence, Abbott viewed the diabetic patient population as a prime and lucrative target for its illicit marketing scheme for TriCor. Thus, a key component of Abbott's unlawful marketing scheme for TriCor has been to promote the drug to be utilized as a first-line drug treatment for diabetic patients.

65. Abbott marketed TriCor as a first-line drug for treatment of diabetic patients despite the lack of an FDA approved indication for such use, and despite the fact that no clinical study data demonstrating TriCor's efficacy or safety in the diabetic patient population as a first line treatment effecting cardiovascular morbidity and mortality was contained in the package insert.

66. As such, Abbott's marketing of TriCor as a first-line drug for treatment of diabetic patients constituted illegal off-label promotion of TriCor.

67. Abbott sales representatives were instructed to attend national/regional meetings quarterly to review and discuss Abbott's marketing strategy. The meetings were run by the sales trainers and members of the Abbott TriCor marketing team. At these meetings, Abbott sales representatives were trained on how to promote TriCor to physicians and were instructed to

focus on the diabetic patient type. Abbott sales representatives were told that the diabetes market was expanding at an increasing rate, and that they should specifically target diabetic patients.

68. As a consequence, TriCor as a first-line drug for the treatment of patients with diabetes was stressed to physicians in sales calls by Abbott's sales representatives from at least 2002 to 2008.

69. Abbott's sales representatives were given specific, detailed instructions for overcoming physician objections to the use of TriCor as a first-line treatment for diabetics, including stated preferences for other pharmaceuticals and objections based on the lack of outcomes data and concerns with product safety. The sales representatives were instructed to open calls with physicians by referencing diabetic patients with mixed dyslipidemia, in order to promote new business by specifically targeting such patients.

70. In order to effectuate its illicit marketing scheme, Abbott instructed its sales representatives to promote TriCor over statins and over other fibrate drugs for diabetic patients. Because TriCor lacked meaningful study data establishing TriCor's safety and efficacy in preventing heart attacks in diabetics, Abbott instructed its sales representatives to use studies of gemfibrozil, another fibrate drug, that did have positive outcomes data to support the use of TriCor, and further directed its sales representatives to make false and misleading statements to physicians regarding the effectiveness of TriCor.

71. Specifically, Abbott sales representatives were instructed by Abbott to promote TriCor to physicians for treatment of diabetics by citing to the VA-HIT Trial (a clinical study that examined the benefits of the fibrate drug gemfibrozil for diabetic patients for a reduction in cardiovascular events), and by claiming it showed that fewer patients had to be treated with a fibrate, like TriCor, compared to a statin before one sees a reduction in events.

72. Because the VA-HIT Trial was a study of the effects of gemfibrozil, *not* TriCor, Abbott's use of the study to support the off-label use of TriCor was patently improper, as well as false and misleading. Abbott used the study as part of its illicit marketing scheme for TriCor in order to respond to doctors' concerns about the lack of positive outcomes data for TriCor because the VA-HIT Trials reported reduced coronary mortality in diabetics and a reduced rate of certain cardiac events with the use of a fibrate drug. However, Abbott's efficacy claims for TriCor based on the VA-HIT Trial were not supported by the data and were contrary to the package insert for TriCor which stated that, "The effect of TriCor on cardiovascular morbidity and mortality and non-cardiovascular mortality has not been established."

73. Abbott also instructed its sales representatives to use the VA-HIT Trial to convince physicians that TriCor was the better drug of choice for diabetic patients, over both statins and gemfibrozil. In support of this effort, Abbott instructed its sales representatives to tell physicians that TriCor would have better results than what was seen with gemfibrizol in the study based upon a false and misleading assertion that TriCor was a stronger fibrate drug than gemfibrizol and would therefore have a greater positive impact on cardiovascular morbidity and mortality in diabetic patients.

74. The release of the Heart Protection Study (HPS) subgroup analysis in 2003 had a major impact on physicians' treatment of diabetic and other high risk patients. The study reported that lowering LDL cholesterol levels with statins in diabetic patients, even those with low or moderate LDL levels, had a significant impact on cardiovascular morbidity and mortality. As a result of the HPS subgroup analysis, many physicians concluded that every high risk patient (diabetic, coronary heart disease) should be placed on a statin as first-line treatment, regardless of the patient's lipid levels. This presented a marketing obstacle for TriCor because TriCor is a

not a statin and is inferior to statins in reducing LDL cholesterol levels. In response, Abbott instructed its sales representatives to either sell physicians on using TriCor instead of a statin by trying to get physicians to focus on other cholesterol types, or to get physicians to prescribe TriCor in addition to a statin.

75. If the patient was already on statin therapy, the representatives were instructed to use the VA-HIT trial to convince the physician to prescribe TriCor in addition to a statin.

76. If the patient was not already being treated with a statin drug, Abbott's sales representatives were instructed to urge the doctors to prescribe TriCor as a first-line treatment for the diabetic patient instead of a statin.

77. To support the off-label use of TriCor instead of a statin in diabetic patients, Abbott's sales representatives were instructed to utilize the Heart Protection Study subgroup analysis (which suggested that gemfibrozil, as compared to the statin Zocor, required fewer patients to treat to reduce the likelihood of an adverse cardiovascular event) to show that fibrates, as a class, are better than statins for the diabetic patient.

78. In addition to utilizing the study results for gemfibrozil to promote a "class effect" for the entire fibrate class (including TriCor), the sales representatives were also told to make efficacy claims for TriCor as a superior fibrate by telling physicians that TriCor is safer and more potent than gemfibrozil. Abbott encouraged the sales representatives to make presentations in which the representatives encouraged physicians to write for TriCor rather than gemfibrozil because TriCor was more efficacious than gemfibrozil in reducing triglycerides and increasing HDL, and because the physicians would see better outcomes in their diabetic patients. Abbott sales representatives were encouraged to utilize actual patients' lab results to illustrate the efficacy of TriCor in order to generate sales.

79. From approximately 2006 through Bergman's termination in 2008, Abbott's sales representatives were provided with a non-branded sales aid to use in the marketing of TriCor. This sales aid furthered Abbott's illegal marketing scheme by compiling a summary of studies supporting the off-label and medically unnecessary uses for TriCor that Abbott wanted its sales representatives to promote. None of the studies in the sales aid was based on any outcomes data for TriCor, and therefore the sales aid to promote TriCor to physicians was false and misleading.

80. To further its illicit marketing scheme for the promotion of TriCor, Abbott distributed a "Paint the Picture" concept of a TriCor patient type, which prominently featured and focused on diabetic patients. The "Paint the Picture" concept was presented at all of Abbott's national and regional sales meetings, and the training involved role playing exercises by sales representatives. Copies of two of the "Paint the Picture" training material handouts are attached hereto and incorporated herein by reference as Exhibits 2 and 3. Exhibit 2, in particular, demonstrates many of the features of Abbott's false and misleading marketing scheme for TriCor.

81. The DAIS Trial was another study provided to Abbott representatives throughout the country. Abbott sales representatives attending Abbott's regional sales meetings were trained by Abbott to use the DAIS study in their sales presentations to promote off-label use of TriCor in diabetics. Although the DAIS Trial is not referenced on the TriCor package insert, Abbott sales representatives were instructed by Abbott to summarize select aspects of the study and to stress the positive points of the study in presentations to physicians.

82. The DAIS Trial study was utilized by Abbott from approximately 2001 until at least 2008. Attached hereto as Exhibit 4 and incorporated herein by reference is a copy of a training handout concerning the DAIS Trial provided to Abbott sales representatives by Abbott.

The DAIS Trial study was utilized by Abbott to try to show "Outcomes for TriCor." Telling of Abbott's off-label intent and intent to mislead in referencing the study, the handout makes no reference to the fact that the study was not evaluated by the FDA as part of the approval of TriCor, and makes no reference to the fact that the TriCor's package insert warns that the effect of TriCor on cardiovascular morbidity and mortality has not been established. Also telling is the fact that the handout instructs sales representatives to "avoid lipid parameter discussions unless brought up by physician." The handout also instructs sales representatives to "verbalize" the results of the study instead of showing the study to physicians. This is so because a review of the study report itself would reveal that the study was conducted on a small number of test subjects, and the study report notes that the study was *not* designed to "examine clinical endpoints" (clinical outcomes).

83. Initially, Abbott's sales representatives were instructed by Abbott to tell physicians that DAIS was the first study to show that treating a Type 2 diabetics with TriCor slows the progression of coronary artery diseases, and that DAIS showed a 40% reduction in the progression of atherosclerosis and a reduction in clinical events by 23%. However, after Abbott's management realized that the information was not recognized by physicians as valid outcomes data because the design of the study was based on angiographic data, Abbott reduced the emphasis on the study. Notwithstanding the reduced emphasis, sales representatives continued to utilize the DAIS Trial in support of sales presentations in an effort to convince physicians that DAIS showed there was positive outcomes data for the treatment of diabetic patients with coronary artery disease, and that they should use TriCor as a first line treatment in diabetic patients.

D. Off-Label Promotion of TriCor for Combination Therapy with Statins

84. Another key component of Abbott's illegal marketing scheme for TriCor was the off-label promotion of TriCor for use in combination therapy with statins. Because TriCor was not approved by the FDA for use in combination with statins, and because the FDA mandated package insert contains a specific safety warning regarding the combined use of TriCor with statins, Abbott's off-label combination therapy marketing strategy included concealment of the off-label nature of the combination and the deceptive minimization of the significant risks of such use combined use.

85. As discussed in the sections above, statins became widely prescribed by physicians as the primary choice for treatment of coronary heart disease and as preventive therapy for high risk patients, such as diabetics. As a result, for those physicians and/or patients that Abbott could not convince to select TriCor over a statin, Abbott sought to have the physician prescribe TriCor *in addition to* a statin. In essence, Abbott adopted an "if you can't beat them, joint them" strategy. Unfortunately for patients, Abbott's strategy exposed them to additional health risks without demonstrated cardiovascular benefit, and subjected patients and third party payors, such as Medicare and Medicaid, to unnecessary medical expenses.

86. Abbott's strategy to enhance TriCor sales by promoting doctors' use of TriCor in combination with statins was outside of the FDA approved indications for TriCor, was inconsistent with the FDA finding that TriCor has no effect on cardiovascular morbidity and mortality and non-cardiovascular mortality, ran afoul of the safety warnings contained in the package insert regarding combined use with statins, and was contrary to the law.

87. From as early as 2002 and continuing to at least 2008, and upon information and belief, continuing to the present, Abbott instructed its sales representatives to promote TriCor for off-label use and medically unnecessary use in combination with statins.

88. The TriCor package insert makes clear that there are significant health risks associated with combined use of TriCor and statins, and that the benefits of TriCor on cardiac outcomes (morbidity and mortality) have not been established. The TriCor package insert specifically cautions that TriCor should be used in combination with statins only in a patient where the physician has determined that the benefits of adding TriCor outweigh the risks of doing so. Abbott, seeking to avoid this obstacle to its marketing scheme for TriCor, minimized information concerning the risks of the combination of TriCor with statins in its marketing efforts and sales representative training, and instructed sales representatives to do the same in their meetings with doctors. Not only did Abbott's actions fail to present a balanced presentation regarding the benefits and risks of TriCor to physicians, it also endangered the very patients Abbott was purportedly trying to help.

89. To maximize the impact of its illegal marketing scheme, Abbott instructed its sales representatives to target physicians who wrote large numbers of prescriptions for statins, and provided its sales representatives with reports providing information regarding the prescribing habits of the physicians within their territory. Attached as Exhibit 5 and incorporated herein by reference, are copies of several sample physician lists that Abbott provided to Amy Bergman for use in targeting physicians.

90. Abbott sales representatives were taught and instructed by Abbott to deceptively promote combination therapy in meetings with physicians without discussing or by minimizing the risks of such use, as well as the critical importance of weighing the benefit against the

increased risk of combination therapy, as described in the package insert, and as required by the FDA and the FDCA.

91. Abbott provided training and scripts to its sales representatives that instructed the representatives on how to interest and encourage doctors to prescribe TriCor in combination with statins. The training and scripts did not mention that the use was off-label.

92. Abbott also provided its sales force with written promotional materials which touted the benefits of combination therapy involving TriCor and statins.

93. Abbott also set up continuing medical education programs for physicians, and used the programs to promote TriCor for off-label and medically unnecessary uses. Abbott would provide a speaker who supported combination therapy, often without discussing the dangers and without providing copies of the package insert which would have revealed the warnings and the information regarding the lack of efficacy of TriCor and the safety concerns.

94. One of the studies that Abbott misleadingly used to promote the off-label combined use of TriCor with statins was the Merck Safari Study. The Merck Safari Study analyzed the effects of Zocor, a statin, in combination with TriCor on triglyceride levels. The Safari Study was not included on the package insert for TriCor. Importantly, the study was not designed to study reduction of coronary heart disease events. Nonetheless, Abbott sales representatives were taught to use the Safari Study in discussions with doctors to promote the combined use of TriCor with statins as safe and effective.

95. Abbott instructed its sales representatives to focus on the fact that there were no reported drug related complications experienced during the Safari Trial. What Abbott did not highlight was that the combined use portion of the study was of very short duration (12 weeks), and that the claims of safety and efficacy that Abbott had its sales representatives make were not

supported by the data and were directly contrary to the warnings on the package insert that the combination of TriCor and statins "should be avoided unless the benefit of further alterations in lipid levels is likely to outweigh the risk of this drug combination."

E. False and Misleading Efficacy Claims

96. An element common to Abbott's illegal marketing scheme for TriCor for both use as a first line treatment in diabetics and for combination therapy with statins was the use of false and misleading efficacy claims for TriCor.

97. Although the TriCor package insert states that TriCor's effect "on coronary heart disease morbidity and mortality and non-cardiovascular mortality has not been established." Abbott nonetheless falsely promoted TriCor, both alone and in combination therapy with statins, as having such positive outcomes.

98. A comprehensive study evaluating the effect of TriCor in type 2 diabetic patients was published in 2005 and confirmed that TriCor lacked efficacy in reducing coronary heart disease in type 2 diabetics. Results from the Fenofibrate Intervention and Event Lowering in Diabetes Study (FIELD Study) were subsequently added to the TriCor package insert, along with a new entry entitled "Important Limitations of Use," which stated "Fenofibrate at a dose equivalent of 145 mg or TRICOR was not shown to reduce coronary heart disease morbidity and mortality in a large, randomized controlled trial of patients with type 2 diabetes mellitus." The new entry in the package insert also observed that study test subjects taking TriCor actually experienced an "increase in total and coronary heart disease mortality," but deemed it not statistically significant.

99. In an effort to blunt the impact of the results of the FIELD Study on its marketing scheme for TriCor, Abbott coached its sales representatives on how to downplay the study's lack of positive outcome data regarding coronary heart disease mortality.

100. Because of the lack of positive cardiovascular outcomes data for TriCor, Abbott m sleadingly used positive outcomes data of studies involving other fibrates drugs (not TriCor, but drugs such as gemfibrozil) to claim the existence of a positive class effect for fibrates on cardiovascular morbidity and mortality. Abbott instructed its sales representatives, and provided them with marketing materials to use, to misleadingly claim that TriCor would have the same positive outcomes as the other fibrate drugs (particularly gemfibrozil), and further instructed its sales representatives to claim that TriCor would produce better outcomes that these other fibrate drugs. Since there was no substantial evidence to support such claims, and since they were contrary to the package insert, it was false and misleading for Abbott to market TriCor in this manner.

101. For example, the Helsinki Trials was a study of gemfibrozil, a fibrate, which showed that gemfibrozil caused a significant reduction in coronary heart disease deaths and heart attacks in the primary component of the study. The Helsinki Study did not involve TriCor. Nonetheless, Abbott sales representatives were taught to use the study to claim that fibrates as a class (including TriCor) caused a significant reduction in cardiac mortality and morbidity.

102. Although TriCor was not involved in the VA-HIT study, Abbott instructed its sales representatives to use the VA-HIT Study to respond to doctors' concerns as to the lack of outcomes data for TriCor. Abbott's efficacy claims based on the VA-HIT Trials were not supported by the data, were contrary to the package insert, and were false and misleading in violation of the FDCA.

103. Abbott instructed sales representatives to use the DAIS Study to suggest that use of TriCor resulted in positive outcome data on coronary mortality and morbidity, although the DAIS Study did not examine cardiac events, mortality or outcomes. The DAIS Study was not

included in the package insert, and Abbott's claims of efficacy were not supported by the data, and were therefore false and misleading in violation of the FDCA.

104. Abbott sales representatives were also trained to use a misleading comparison of the Merck Heart Protection Study involving a statin, to the VA-HIT trial involving gemfibrozil, a fibrate, to try to convince doctors that TriCor was a superior drug for physicians to use in treating their diabetic patients. The premise of the comparison was to suggest that fibrate drug outcomes (as a class) were superior to statins based upon a comparison of the so-called "numbers needed to treat" before a cardiac event reduction was realized. This use of the Merck Heart Protection, as well as the VA-HIT trial, was patently improper, false and misleading, and made unsubstantiated efficacy claims for TriCor.

105. The ACCORD Study, which evaluated the effects of combination lipid therapy in type 2 diabetics using TriCor and the statin drug simvastatin, was published in 2010. The study failed to generate positive outcomes data for the combination therapy. The conclusion of the study authors was that the "combination of fenofibrate [TriCor] and simvastatin did not reduce the rate of fatal cardiovascular events, nonfatal myocardial infarction [heart attacks], or nonfatal stroke, as compared with simvastatin alone. These results do not support the routine use of combination therapy with fenofibrate and simvastatin to reduce cardiovascular risk in the majority of high risk patients with type 2 diabetes." Attached as Exhibit 6 and incorporated by reference herein is a copy of the New England Journal of Medicine reporting the results study.

106. As a consequence of the results of the ACCORD Study, the FDA issued a Drug Safety Communication informing medical providers and the public regarding the results of the ACCORD study, making changes to the package insert for TriCor's more recent cousin drug Trilipix (fenofibric acid), and requesting providers report adverse events. A copy the FDA Drug

Safety Communication is attached as Exhibit 7, and incorporated herein by reference. The FDA did not issue a similar alert for TriCor because TriCor was not approved for combination therapy with statins. Additionally, the package insert for TriCor had been amended in September 2011, and included increased warnings regarding a lack of efficacy of TriCor in treating type 2 diabetic patients. A copy of the September 2011 TriCor package insert is attached at Exhibit 8 and incorporated herein by reference.

107. The failed ACCORD and FIELD studies also prompted researchers to explore why fibrate use in the United States has increased despite the lack of positive outcomes data, while the use of fibrates in Canada has remained stable. The study, Use of Fibrates in the United States and Canada was published in the Journal of the American Medical Association in March 2011. The study found that "the use of fibrates steadily increased during the last decade in the United States but not in Canada, even as evidence emerged to question the benefits of newer fibrates in the contemporary statin era. Increased use in the United States appears to be largely driven by a steady increase in fenofibrate use of nearly 200% during the study period [2002 through 2009]. The study goes on to report that fenofibrate comprised 47.9% of the fibrate prescriptions in the United States in 2002, and comprised 65.2% of the fibrate prescriptions in the United States in 2009. The study continues by noting that, "This pattern is paradoxical to declines that might have been expected because the only clinical evidence for fenofibrate during our study period was the FIELD trial, which failed to find a significant reduction in the primary end point of coronary events in a diabetic population." The study observes that "the use of fenofibrate was increasing both before and after the FIELD study were published, *suggesting that other factors beside clinical trial evidence are influencing fibrate prescription patterns*." The study continues that "brand name fenofibrate (mainly TriCor) was the predominate

fenofibrate product used in the United States, accounting for 90% of the fenofibrate market share until recently." In the study conclusion, the authors note that fenofibrate dominates the market despite it having the least supportive clinical outcome evidence." A copy of the study is attached hereto as Exhibit 9 and incorporated by reference.

108. The fenofibrate paradox (increased use of fenofibrate in the United States despite negative trial results) also garnered the attention of the popular press in 2011. In a story by ABC News correspondent Jane E. Allen in March 2011, entitled *Doctors Push Fibrate Cholesterol Drugs Despite Scant Evidence of Effectiveness,* she reports on the FIELD and ACCORD study results, and includes quotes from several notable physicians concerning the questionable use of TriCor. One of those quotes is from Dr. Steven E. Nissen, Chairman of Cardiovascular Medicine at the Cleveland Clinic, who states: "This is a classic example of marketing triumphing over science." The article also includes quotes and comments from TriCor's proponents, who observe the TriCor has its valid uses — and TriCor does have its valid uses. Unfortunately for countless patients and for the American taxpayers, Abbott was not content with marketing TriCor for just those legitimate uses, and instead sought to enrich itself at the expense of patients and Government and State funded health insurance programs by marketing TriCor for off-label and medically unnecessary uses.

F. Overcoming the Pharmacist Obstacle

109. One of the obstacles that Abbott encountered in implementing its illicit scheme to promote TriCor for off-label combination therapy with statins was pharmacists questioning the combination due to the safety issues with combination therapy.

110. As a prescription drug, prescriptions for TriCor would generally be filled by a pharmacist. Many pharmacies have systems in place to alert pharmacists when dangerous or

unsafe combinations of drugs are prescribed by physicians for their customers. Because of the safety warnings regarding combined use of TriCor with statins in the TriCor package insert, in those pharmacies with alert systems, the pharmacists would receive alerts when filling prescriptions for TriCor when the patient was also taking a statin. Other pharmacists, because of their familiarity with the warnings contained in the package insert, would also question the combination therapy.

111. Upon receiving an alert regarding the potentially dangerous and unsafe combination of TriCor and a statin when filling a prescription for TriCor, or otherwise being aware of the danger, pharmacists would contact physicians to alert them of the danger and to confirm whether the physicians still wanted the prescription for TriCor filled.

112. As a result of pharmacists contacting physicians questioning the combination of TriCor with a statin, physicians who had not been informed of the dangers of combination therapy or its off-label nature by Abbott sales representatives, became aware. This resulted in resistance to combination therapy by those physicians, and resulted in push-back by physicians toward the Abbott sales representatives.

113. In some instances, pharmacists simply refused to fill prescriptions for combination therapy.

114. Abbott realized that if it did not address this issue with pharmacists, its plan for expansion of combination therapy for TriCor would be hampered.

115. To address this issue in Amy Bergman's territory, Abbott identified pharmacists in Palm Beach County, Florida, who would not process prescriptions for TriCor in combination with a statin at all or without physician verification. Abbott then had Bergman assist with setting up a seminar for local pharmacists and Abbott paid a physician to make presentations to the

pharmacists regarding the use of TriCor in combination therapy with statins. The presentation promoted the combined use of TriCor with statins, represented the use as safe, and did not include the package insert and minimized the information regarding the possible dangers of combination therapy.

116. As a consequence, pharmacist resistance to filling prescriptions for the off-label combination therapy of TriCor with a statin was substantially reduced in Bergman's territory.

117. Upon information and belief, similar pharmacist seminars or related efforts were taken by Abbott in other territories around the country to address the issue of pharmacist resistance to filling prescriptions for TriCor combination therapy with statins.

G. Concealment of the Off-Label Promotion and Abbott's Illegal Marketing of TriCor

118. Abbott actively sought to conceal the existence of the off-label discussions regarding combination therapy its sales representatives were having with physicians. Although Abbott's sales representatives were required to make "call notes" after meetings with doctors, Abbott instructed its sales representatives not to openly record the existence of off-label discussions in their call notes. Whenever Abbott representatives had off-label discussions with doctors concerning combination therapy of TriCor with statins, they were instructed to use the code "BOR" [benefits outweigh risks] or similar codes in their call notes. Attached hereto as Exhibit 10 is an example call note evidencing the use of the "BOR" code.

119. Further, upon information and belief, in 2009, in an effort to conceal false, misleading and off-label marketing materials Abbott had provided its sales representatives to use in marketing TriCor, Abbott directed its sales representatives to return all copies of a non-branded sales aid that Abbott had provided to its sales representatives to use in promoting TriCor for off-label and medically unnecessary uses. The non-branded sales aid in issue, an aid which

Amy Bergman had been provided by Abbott and used in her marketing of TriCor, contained a number of studies of other drugs (including the VA-HIT and Heart Protection Studies), and was designed to promote TriCor for off-label and medically unnecessary uses in violation of the marketing restrictions under the FDCA and FDAMA.

H. Illegal Payments to Doctors

120. As part of its illegal marketing scheme for TriCor, Abbott made and caused others to make illegal kickbacks and prohibited remuneration to physicians in order to induce them to prescribe TriCor for Medicare, Medicaid and other Government health insurance programs' covered patients, including for off-label and medically unnecessary use.

121. Federal statutes and regulations prohibits the offer or payment of remuneration of any kind, including kickbacks and bribes, either directly or indirectly, cash or in kind, in order to induce a provider to order or prescribe an item or service which may be paid for by the Medicare, Medicaid and certain other Government health insurance programs. This prohibition includes offering or paying remuneration to induce a physician to order or prescribe off-label and/or medically unnecessary services and drugs, as well as for on-label and medically necessary services and drugs. This is so because kickbacks have the effect of reducing a patient's healthcare choices and quality of care by corruptly influencing physicians to steer patients to products based on the physician's own financial interests, rather than on the patient's medical needs. Kickbacks also undermine the physician's own medical judgment as to which drug to prescribe, sometimes subtlety and even unconsciously. Kickbacks also tend to increase the costs to Government health insurance programs by increasing the cost of health care.

122. Despite the prohibition on kickbacks, Abbott directed its TriCor sales representatives to identify doctors who wrote a large number of prescriptions for statins or for other cholesterol drugs, and then encouraged the sales representatives to find ways to financially

induce the doctors to write prescriptions for TriCor. With respect to those physicians that were already writing prescriptions for TriCor, Abbott instructed its sales representatives to find ways to financially reward those doctors for writing prescriptions for TriCor, and to incentivize them to write more prescriptions for other patients.

123. To carry out Abbott's kickback plan, Abbott sales representatives would have team meetings to review prescribing habits of doctors and to determine which doctors to provide financial inducements. Abbott sales representatives and managers referred to this as keeping or putting a physician "on Abbott's payroll." Such meetings and discussions specifically occurred in Amy Bergman's sales region, and on information and belief, occurred in Abbott's other sales regions throughout the country.

124. Abbott's sales representatives were given quarterly allowances to use to provide financial incentives to physicians (referred to as their "war chest"), and also had access to additional funds through a third party vendor Abbott provided funds for sales representatives to use for meetings and dinner programs. The financial incentives provided to physicians took a number of forms, and depending on the time period and Abbott's sensitivity to regulatory scrutiny at that particular time, the type of incentive was limited only by the imagination of the particular sales representative and their manager. By way of example, attached as Exhibit 11, and incorporated herein by reference, are sale representative proposals for physician inducements made by sales representatives in Amy Bergman's region. The lists include: fly-away programs where doctors would spend the weekend at a resort/hotel and receive an honorarium or CME credits, boat and fishing trips, golf outings, sporting events and theater events and dinner events.

125. Among these types of inducements that Amy Bergman is personally aware were provided by Abbott to physicians were lunches, dinners, trips to resorts for conferences, theater

programs, professional football games and concerts. These events were usually accompanied by a brief talk about TriCor.

126. Abbott's TriCor sales representatives were also encouraged to organize dinner "roundtable" programs for doctors. Financing for these dinner roundtables was provided and approved by Abbott's central office.

127. The speaker for the dinner roundtable would be a doctor targeted for inducement by Abbott. The targeted doctor would receive $500 or more as a speaker fee and free dinner at an expensive restaurant. To provide an audience for the roundtable, the speaker would invite staff members, friends and fellow practitioners, including doctors in specialties unrelated to coronary care or cholesterol/triglyceride management. The targeted doctor would be provided with a study to review and discuss at the roundtable. Often, the study would be selected because it supported the off-label use of TriCor. Amy Bergman organized an number of these dinners at Abbott's direction.

128. Abbott also used, at various times, preceptorships to provide payments to doctors. The preceptorships involved paying a physician a fee for allowing an Abbott sales representative to "shadow" them for a day. In exchange, the physician would receive a payment of between $300 and $500. The use of preceptorships would be targeted. Either high volume TriCor prescription writers would be selected to serve as preceptors for a sales representative, or doctors were recruited as preceptors for the purpose of providing them incentive to increase their TriCor prescriptions. Amy Bergman was instructed by Abbott to utilize preceptorships for this purpose, and is personally aware of preceptorships being used for this purpose.

129. Abbott also used "Advisory Board Meetings" in vacation cities as a way to reward its high prescribing physicians. Abbott would pay doctors an "honorarium" to attend the

Advisory Board Meetings, and provided them transportation to the meeting, or funds to do so. Physicians were selected for the Advisory Board Meetings based upon their status as high prescribers of TriCor, and not upon academic or peer standing. Abbott would instruct its sales representatives, including Amy Bergman, to select and nominate a high prescriber in their territory to attend the Advisory Board Meetings.

VI. FALSE CLAIMS

130. Abbott, through the successful execution of its unlawful TriCor marketing scheme, knowingly caused prescriptions to be written for TriCor and claims for reimbursement to be submitted to the United States and the States that would not have been written or submitted but for Abbott's unlawful conduct.

131. Prescriptions for TriCor which resulted from Abbott's illicit off-label marketing of TriCor for use as a first-line therapy in diabetic patients, and which resulted from its illicit off-label marketing of TriCor for use in combination therapy with statins, were not for medically accepted indications and therefore were not eligible for reimbursement under Medicaid, Medicare or other federal health care programs.

132. As a direct result of Abbott's improper off-label and misleading marketing practices for TriCor, and as a direct result of illegal inducements provided by Abbott to physicians to prescribe TriCor, health insurance programs funded by the United States and/or the States, including but not limited to Medicare, Medicaid, TRICARE, and the Federal Employees Health Benefit Program, received and paid false and fraudulent reimbursement claims for TriCor prescriptions written to those programs' beneficiaries. The United States and the States would not have paid such claims but for Abbott's illegal and fraudulent conduct.

133. Abbott did not directly submit the false claims for TriCor to the federal and state health insurance programs; however, Abbott knew — and in fact it was Abbott's goal — that its

illegal marketing scheme would cause the submission of many thousands of false claims to be submitted to Medicare, Medicaid, and to other Government-funded and State-funded health insurance programs. Abbott knew that the more prescriptions that were written for TriCor, and the more claims that were paid by the United States and the States through their health insurance programs, the more profits that Abbott would realize from selling TriCor.

134. Abbott marketed TriCor for illegal off-label and medically unnecessary uses to many physicians around the United States. Those physicians included, but were not limited to, the following:

Arman, Lynda
Antellis, Eugene
Apostolopoulos, Neostolopoulis
Arena, Joseph
Baine, Stuart
Baker, Leah
Barish, Susan
Baum, Seth
Berenson, Bruce
Berenson, Scott
Bruzzo, Michele
Caridi, Steven
Cohen, Meyer
Cohen, Steven
Cohen, Roy
Colton, Robert
Crescetelli, John
Deitsch, Gregory
Demarchi, William
Depodesta, Craig
Devine, Charles
Devon, Jeffrey
Diamond, Paul
Ehrlich, Laurence
Felker, David
Figueira, Christina
Gherghina, Valentina

Gomer, Alan
Grenn, Gordon
Gross, Jeffrey
Gruss, William
Gutierrez, Maria
Hevert, David
Hammelstein, Stuart
Horowitz, Barry
Jacob, Marty
Johnson, Charles
Jurado, Maria
Kaufmann, John
Lampert, Mitchell
Laracuente, Ronald
Lavernia, Frank
Levin, Bruce
Levin, Richard
Levinson, David
Lopez, Enrique
Lopez-Ivern, Fernando
Lopez-Padillo, Fran
Macia, Jorge
Mellman, Michael
Milbauer, David
Monahan, Kevin
Moraes, Brian
Neuman, David
Nicursor, Ieremia
Portnoy, Dana
Rathbun, Kathleen
Rebello, Brian
Remenson, Ella
Rogovin, Mark
Rooptaz, Sibia
Rosenberg, Marc
Ross, Steven
Rowland, William
Santa Maria, Roderick
Scanlon, Mary
Schwartz, Paul

Seidman, Barry
Slotnick, David
Speizman, David
Spirazza, Carl
Sperduto, Joseph
Stampalia, Anthony
Strobis, John
Trejo, Rodolfo
Tumminia, Louis
Ukani, Zaib
Weatherford, Gregory
Weisman, Neal
Widdows, Joanna
Willey, Michele
Wishnov, Bruce

135. As a consequence of Abbott's illegal marketing scheme for off-label and medically unnecessary uses of TriCor, many physicians around the United States prescribed TriCor for off-label and medically unnecessary uses. These physicians included, but were not limited to the following:

Arena, Joseph
Barish, Susan
Berenson, Bruce
Caridi, Steven
Cohen, Meyer
Cohen, Steven
Depodesta, Craig
Devine, Charles
Felker, David
Hevert, David
Horowitz, Barry
Ieremia, Nicursor
Johnson, Charles
Lavemia, Frank
Levin, Richard
Levinson, David
Lopez, Enrique
Lopez-Padillo, Franco

Macia, Jorge
Mellman, Michael
Neuman, David
Portnoy, Dana
Ross, Steven
Seidman, Barry
Speizman, David
Sperduto, Joseph
Spirazza, Carl
Tumminia, Louis
Wishnov, Bruce

136. The following physicians informed Abbott sales representatives that they had prescribed TriCor for diabetic patients as a result of Abbott's marketing of TriCor as a first-line treatment for diabetics:

Berenson, Bruce
Cohen, Steven
Hevert, David
Ieremia, Nicursor
Johnson, Charles
Lavernia, Frank
Portnoy, Dana
Seidman, Barry
Spirazza, Carl
Wishnov, Bruce

VII. GOVERNMENT FUNDED HEALTH INSURANCE PROGAMS DAMAGED BY ABBOTT'S SCHEME

137. The United States and the States reimburse all or a portion of the cost of prescription drugs under several health care programs, including, but not limited to, Medicare, Medicare Part D, Medicaid, TRICARE and the Federal Employees Health Benefit Program.

138. The United States and the States, through the Medicare, Medicaid, TRICARE, the Federal Employees Health Benefit Program, and other Government and State health insurance programs, are among the principal purchasers of TriCor in the United States.

A. Medicare and Medicare Part D

139. Medicare is a government health insurance program administered by the United States Department of Health and Human Services (HHS) through the Centers for Medicare and Medicaid Services (CMS). The health insurance provided to beneficiaries of the Medicare program is paid in whole or in part by the United States. Medicare was enacted to provide payment for medical services, durable medical equipment, inpatient drugs and other related health items for individuals 65 and over, and well as for certain disabled or seriously ill individuals.

140. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"). Title I of the MMA created new outpatient prescription drug coverage under Medicare for Medicare beneficiaries ("Medicare Part D").

141. Medicare Part D went into effect on January 1, 2006. The Program is administered by HHS through CMS. For "dual eligibles," defined as individuals who received prescription drug coverage under Medicaid in addition to Medicare coverage for other health care in 2005, enrollment in Medicare Part D was compulsory. Such beneficiaries were automatically switched to the Part D plans for 2006 and commenced receiving comprehensive prescription drug coverage under Medicare Part D.

142. As a direct, proximate and intended result of Abbott's illegal TriCor marketing scheme, non-reimbursable claims for TriCor have been submitted to and paid by CMS under the Medicare program.

143. Each off-label, medically unnecessary or kickback tainted claim for a TriCor prescription that Abbott knowingly caused to be submitted to the Medicare Program for

reimbursement constitutes a false claim for which Abbott is accountable under the Federal False Claims Act.

B. Medicaid

144. Medicaid, which was enacted under Title XIX of the Social Security Act, is a program which provides medical assistance for certain individuals and families with low incomes and resources. The Medicaid Program became law in 1965 as a jointly funded cooperative venture between the federal and state governments to assist states in the provision of adequate medical care to eligible needy Americans.

145. The Medicaid Program is administered and funded jointly by the United States through CMS, and by the States. While specific Medicaid coverage guidelines vary from state to state, Medicaid's coverage is generally modeled after Medicare's coverage, except that Medicaid usually provides more expansive coverage than does Medicare.

146. The States statutorily limit, with narrow exceptions not applicable here, Medicaid reimbursement for prescription drugs to those uses approved by the FDA.

147. As a direct, proximate and intended result of Abbott's illegal TriCor marketing scheme, non-reimbursable claims for TriCor have been submitted to and paid by CMS and the States under the Medicaid program.

148. Each off-label, medically unnecessary or kickback tainted claim for a TriCor prescription that Abbott knowingly caused to be submitted to the Medicaid program for reimbursement constitutes a false claim for which Abbott is accountable under both the Federal False Claims Act and the false claims acts of the various states.

C. TRICARE

149. TRICARE, formerly known as CHAMPUS, is a managed care program established by the United States Department of Defense. 10 U.S.C. § 1071-1110. TRICARE

provides health care benefits to eligible beneficiaries, which include, among others, active duty service members, retired service members, and their dependents.

150. The regulatory authority establishing the TRICARE program does not cover drugs not approved by the FDA. See 32 C.F.R. § 199.4(g)(15)(i)(A).

151. TRICARE does not cover drugs used for off-label indications unless such off-label use is proven medically necessary and safe and effective in medical literature, national organizations, or technology assessment bodies.

152. As a direct, proximate and intended result of Abbott's illegal TriCor marketing scheme, non-reimbursable claims for TriCor have been submitted to and paid by the TRICARE program.

153. Each off-label, medically unnecessary or kickback tainted claim for a TriCor prescription that Abbott knowingly caused to be submitted to the TRICARE program for reimbursement constitutes a false claim for which Abbott is accountable under the Federal False Claims Act.

D. Federal Employees Health Benefits Program

154. The Federal Employees Health Benefits Program (FEHBP) is a federally funded health care program established by Congress in 1959, pursuant to the Federal Employees Health Benefits Act. 5 U.S.C.§ 8901 *et seq.*

155. The United States Office of Personnel Management (OPM) administers this program and contracts with various health insurance carriers to provide services to FEHBP members.

156. Funds for the FEHBP are maintained in the Employees Benefits Fund, which OPM administers.

157. The Employees Benefit Fund, which is held and invested by the United States Treasury, is the source of all relevant payments to insurance carriers for services rendered to FEHBP members.

158. Benefits under the FEHBP are payable only when medically necessary to prevent, diagnose, or treat an illness, disease, injury, or condition. During the relevant time period, the benefit plans for the major FEHBP insurance carriers (Blue Cross and Blue Shield, Government Employees Hospital Association, Inc., and Mail Handlers Benefit Plan) specifically provided that they did not cover services, drugs, or supplies that are not medically necessary.

159. As a direct, proximate and intended result of Abbott's illegal TriCor marketing scheme, non-reimbursable claims for TriCor have been submitted to and paid by the FEHBP.

160. Each off-label and medically unnecessary claim for a TriCor prescription that Abbott knowingly caused to be submitted to the FEHBP for reimbursement constitutes a false claim for which Abbott is accountable under the Federal False Claims Act.

COUNT ONE

Violation of False Claims Act, 31 U.S.C. § 3729(a)(1)

161. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

162. The False Claims Act, 31 U.S.C. § 3729(a)(1), provides that any person who knowingly submits or causes to be presented to the United States for payment or approval a false or fraudulent claim is liable to the United States for a civil penalty of not less than $5,500 and not more than $11,000 (adjusted as set forth in 28 C.F.R. § 85.3) for each such claim, plus three times the amount of damages sustained by the United States because of the false claims.

163. The False Claims Act allows any person with knowledge of a false or fraudulent claim against the United States to bring an action in the United States District Court for herself

and for the United States and to share in any recovery as authorized by 31 U.S.C. § 3730. There are no bars to recovery under 31 U.S.C. § 3730(e) and Bergman is an original source as defined in the statute. Bergman claims entitlement to a portion of any recovery obtained by the United States as Relator and original source in this action.

164. As a direct, proximate and intended result of Abbott's illegal TriCor marketing scheme described above, non-reimbursable claims for TriCor have been submitted to and paid by the United States under Medicare, Medicaid, TRICARE and the FEHBP.

165. By virtue of the acts described above, Abbott knowingly caused to be presented to officers or employees of the United States government false and/or fraudulent claims for the improper payment or approval for TriCor based upon prescriptions that were for off-label and medically unnecessary purposes, and/or which were procured through the payment of prohibited remuneration and inducement in violation of the Medicare and Medicaid Anti-kickback statute

166. The United States, unaware of the falsity of the claims and statements made or caused to be made by Abbott, and in reliance on their accuracy, paid and continues to pay claims that would not have been paid but for Abbott's illegal marketing scheme for TriCor.

167. The amounts of the false or fraudulent claims were material. By reason of Abbott's acts, the United States has been damaged in a substantial amount. Federal health insurance programs have paid substantial amounts for prescriptions that were induced and procured by Abbott's unlawful marketing scheme and which should not have been paid.

WHEREFORE, Plaintiff-Relator Amy Bergman demands that this Court enter judgment against defendant Abbott Laboratories in an amount equal to three times the amount of damages sustained by the United States because of Abbott's actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729, and awarding to Amy

Bergman the maximum amount allowed pursuant to 31 U.S.C. §3730(d) of the False Claims Act, plus all her costs, expenses, and attorneys' fees to the extent permitted by law, and that the United States and Amy Bergman be awarded such other and further relief as this Court deems just and proper.

COUNT TWO

Violation of False Claims Act, 31 U.S.C. § 3729(a)(2)

168. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

169. The False Claims Act, 31 U.S.C. § 3729(a)(2), provides that any person who knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government is liable to the United States for a civil penalty of not less than $5,500 and not more than $11,000 (adjusted as set forth in 28 C.F.R. § 85.3) for each such claim, plus three times the amount damages sustained by the United States because of the false claims.

170. The False Claims Act allows any person with knowledge of a false or fraudulent claim against the United States to bring an action in the United States District Court for herself and for the United States and to share in any recovery as authorized by 31 U.S.C. § 3730. There are no bars to recovery under 31 U.S.C. § 3730(e) and Bergman is an original source as defined in the statute. Bergman claims entitlement to a portion of any recovery obtained by the United States as Relator and original source in this action.

171. By virtue of the acts described above, Abbott knowingly caused false records or statements to be made to get false or fraudulent claims for the improper payment or approval of for prescriptions for Tricor paid or approved by the government, such claims for TriCor being based upon prescriptions that were for off-label and medically unnecessary purposes, and/or

which were procured through the payment of prohibited remuneration and inducement in violation of the Medicare and Medicaid Anti-kickback statute.

172. The United States, unaware of the falsity of the claims and statements made or caused to be made by Abbott, and in reliance on their accuracy, paid and continues to pay claims that would not have been paid but for Abbott's illegal marketing scheme.

173. The amounts of the false or fraudulent claims were material. By reason of Abbott's acts, the United States has been damaged in a substantial amount. Federal health insurance programs have paid substantial amounts for prescriptions that were induced and procured by Abbott's unlawful marketing scheme and which should not have been paid.

WHEREFORE, Plaintiff-Relator Amy Bergman demands that this Court enter judgment against defendant Abbott Laboratories in an amount equal to three times the amount of damages sustained by the United States because of Abbott's actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729, and awarding to Amy Bergman the maximum amount allowed pursuant to 31 U.S.C. §3730(d) of the False Claims Act, plus all her costs, expenses, and attorneys' fees to the extent permitted by law, and that the United States and Amy Bergman be awarded such other and further relief as this Court deems just and proper.

COUNT THREE

Violations of the Illinois False Claims Act
740 ILCS 175, *et seq.*

174. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

175. This Count is brought by Plaintiff-Relator Bergman in the name of the State of Illinois under the *qui tam* provisions of 740 ILCS 175/4 for Defendant's violation of 740 ILCS 175/3.

176. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Illinois, including TriCor.

177. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175/3 (a)(1)-(3), specifically provide that any person who:

> (1) Knowingly presents, or causes to be presented, to an officer or employee of the State or member of the Guard a false or fraudulent claim for payment or approval;...
>
> (2) Knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State; ...
>
> (3) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid;...
>
> (a) is liable to State for civil penalty of not less than $5,500 and not more than $11,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

178. By virtue of the above-described acts, among others, Defendant Abbott knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Illinois, for TriCor.

179. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of Illinois;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state. by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

180. The amounts of the false or fraudulent claims to the State of Illinois were material.

181. Plaintiff State of Illinois, being unaware of the falsity of the claims caused to be submitted by the Defendant, and in reliance on the accuracy thereof paid and continues to pay for non-covered and non-reimbursable claims for TriCor.

COUNT FOUR

Violations of the California False Claims Act

Cal. Gov. Code §§12650, *et seq.*

182. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

183. This Count is brought by Plaintiff-Relator Bergman in the name of the State of California under the *qui tam* provisions of the California False Claims Act, California Government Code §12651(a), pursuant to which treble damages and civil penalties are sough .

184. Defendant Abbott at all times relevant to this action sold and marketed, and contin ues to sell and market, pharmaceuticals, including TriCor, in the State of California.

185. Cal. Govt. Code §12651(a) provides liability for the costs of a civil action, a civil penalty of up to $10,000 and treble damages for all damages sustained by the state for any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or any political subdivision;

(3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision;

(4) is a beneficiary of an inadvertent submission of a false claim, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the polit cal subdivision within a reasonable time after discovery of the false claim.

186. By virtue of the above-described acts, among others, Defendant Abbott knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of California, for TriCor.

187. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of California;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

188. The amounts of the false or fraudulent claims to the State of California were material.

189. Plaintiff State of California, being unaware of the falsity of the claims caused to be submitted by Defendant Abbott and in reliance, on the accuracy thereof paid and continues to pay for non-covered and non-reimbursable claims for TriCor..

COUNT FIVE

Violations of the Delaware False Claims and Reporting Act
6 Del. C. §§1201, *et seq.*

190. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

191. This Count is brought by Plaintiff-Relator Bergman in the name of the State of Delaware under the *qui tam* provisions of the Delaware False Claims and Reporting Act, Delaware Statute Title VI, Section 1201.

192. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Delaware, including TriCor.

193. The Delaware False Claims and Reporting Act, 6 Del Code Ann. §1201(a)(1) provides for liability for any person who:

> knowingly presents or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval; ... shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of the actual damages which the Government sustains because of the act of that person.

194. The Delaware False Claims and Reporting Act, 6 Del. C. 1201(a)(2) provides for liability for any person who;

> knowingly makes, uses or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; ...shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of the actual damages which the Government sustains because of the act of that person.

195. The Delaware False Claims and Reporting Act, 6 Del. C. §1201(a)(3), provides for liability for any person who;

> Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; ... shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of the actual damages which the Government sustains because of the act of that person.

196. By virtue of the above-described acts, among others, Defendant Abbott knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Delaware, for TriCor.

197. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of Delaware;

- knowingly made, used or caused to be made or used false records to get false claims paid;

- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,

- failed to disclose the existence of the false claims it has caused to be presented.

198. The amounts of the false or fraudulent claims to the State of Delaware were material.

199. Plaintiff State of Delaware, being unaware of the falsity of the claims caused to be submitted by the Defendant, and in reliance on the accuracy thereof paid and continues to pay for non-covered and non-reimbursable claims for TriCor.

COUNT SIX

Violations of the District of Columbia False Claims Act
D.C. Code §§2-308.14, *et seq.*

200. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

201. This Count is brought by Plaintiff-Relator Bergman in the name of the District of Columbia under the *qui tam* provisions of D.C. Stat. §2-308.03 *et seq.*

202. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the District of Columbia, including TriCor.

203. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(1)-(3), specifically provides in part;

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of

the act of that person. A person who commits any of the following acts shall a so be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for *a* civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:

(1) Knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval.

(2) Knowingly makes, uses. or causes to be made or used, a false record or statement to get a false claim paid or approved by the District.

(3) Conspires to defraud the District of Columbia by getting a false claim allowed or paid by the District.

204. By virtue of the above-described acts, among others, Defendant Abbott knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers. employees or agents of the District of Columbia. for TriCor.

205. Specifically, Defendant has:

- caused thousands of fake claims to be presented to the District of Columbia;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented..

206. The amounts of the false or fraudulent claims to the District of Columbia were material.

207. Plaintiff District of Columbia, being unaware of the falsity of the claims caused to be submitted by the Defendant, and in reliance on the accuracy thereof paid and continues to pay for non-covered and non-reimbursable claims for TriCor.

COUNT EIGHT

Violations of the Florida False Claims Act

Fla. Stat. §§68.081, *et seq.*

208. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

209. This Count is brought by Plaintiff-Relator Bergman in the name of the State of Florida under the *qui tam* provisions of Florida False Claims Act, Fl. Stat. §§ 68.031-68.09.

210. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Florida, including TriCor.

211. Fla. Stat § 68.082(2)(a)-(c) provide liability for any person who:

> (a) Knowingly presents, or causes to be presented, to an officer or employee of an agency, a false or fraudulent claim for payment or approval; ... Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;.. , is liable to the state for a civil penalty of not less than $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.
>
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency:... is liable to the state for a civil penalty of not less than $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

> (c) Conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid; ...is liable to the state for a civil penalty of not less than $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains because of the act or omission of that person is liable to the state for a civil penalty of not less than $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

212. By virtue of the above-described acts, among others, Defendant Abbott caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Florida, for TriCor.

213. Specifically, Defendant has:

a. caused thousands of false claims to be presented to the State of Florida;

b. knowingly made, used or caused to be made or used false records to get false claims paid;

c. conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,

d. failed to disclose the existence of the false claims it has caused to be presented.

214. The amounts of the false or fraudulent claims to the State of Florida were material.

215. Plaintiff State of Florida, being unaware of the falsity of the claims caused to be submitted by the defendant, and in reliance on the accuracy thereof paid and continues to pay for non-covered and non-reimbursable claims for TriCor.

COUNT EIGHT

Violations of the Georgia State False Medicaid Claims Act

Ga. Code §§49-4-168, *et seq.*

216. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

217. This is a *qui tam* action brought by brought by Bergman and the State of Georgia to recover treble damages, civil penalties and the cost of this action, under the Georgia State False Medicaid Claims Act, Ga. Code §§49-4-168, *et seq.*

218. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Georgia, including TriCor.

219. Georgia State False Medicaid Claims Act, O.C.G.A. § 49-4-168.1(a), specifically provides in part:

(a) Any person who:

(1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;

(3) Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid;

...shall be liable to the State of Georgia for a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each false or fraudulent claim, plus three times the amount of damages which the Georgia Medicaid program sustains because of the act of such person.

220. By virtue of the acts described above, Defendant knowingly presented, or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

221. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of Georgia;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

222. For example, TriCor prescriptions for the purposes of non-medically accepted uses would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendant. As a result of this illegal scheme, these claims were improper in whole pursuant to the Georgia State False Medicaid Claims Act.

223. By virtue of the acts described above, Abbott knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

224. Each prescription that was written as a result of Defendant's illegal marketing practices represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions for non-medically accepted uses submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

225. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Abbott's conduct. The false claims were presented by many separate entities, and over many years.

226. The Georgia State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Abbott, paid and continues to pay the claims that would not be paid but for Abbott's false and illegal off-label marketing practices.

227. By reason of Abbott's acts, the Georgia State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

228. Georgia is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Abbott.

229. Defendant did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue. Relator is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Georgia State False Medicaid Claims Act on behalf of herself and the State of Georgia.

COUNT NINE

Violations of the Hawaii False Claims Act

HRS §§661-21, *et seq.*

230. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

231. This Count is brought by Plaintiff-Relator Bergman in the name of the State of Hawaii under the *qui tam* provisions of Hawaii False Claims Act. Haw. Rev. Stat. §661-21 *et seq.*

232. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Hawaii, including TriCor. The Hawaii False Claims Act, Haw. Rev. Stat § 661-21(0(1)-0) specifically provides that any person who:

(1) Knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

(3) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid;

(4) Shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the state sustains due to the act of that person.

233. By virtue of the above-described acts, among others, Defendant Abbott knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Hawaii, for TriCor.

234. Specifically, Defendant has:

- caused thousands of false claims to he presented to the State of Hawaii;

- knowingly made, used or caused to be made or used false records to get false claims paid;

- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,

- failed to disclose the existence of the false claims it has caused to be presented.

235. The amounts of the false or fraudulent claims to the State of Hawaii were material.

236. Plaintiff State of Hawaii, being unaware of the falsity of the claims caused to be submitted by Defendant, and in reliance on the accuracy thereof paid and continues to pay for non-covered and non-reimbursable claims for TriCor.

COUNT TEN

Violations of the Louisiana Medical Assistance Programs Integrity Law
La. R.S. §§46:437, *et seq*.

237. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

238. This Count is brought by Plaintiff-Relator Bergman in the name of the State of Louisiana under the *qui tam* provisions of the Louisiana Medical Assistance Programs Integrity Law, Louisiana Rev. Stat. § 46-437 *et seq*.

239. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Louisiana, including TriCor.

240. The Louisiana False Claims And Medical Assistance Programs Integrity Law, La. Rev. Stat. § 46-438.3 provides:

(A) No person shall knowingly present or cause to be presented a false or fraudulent claim.

(B) No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds.

(C) No person shall knowingly make, use, or cause to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the medical assistance programs.

241. By virtue of the above-described acts, among others, Defendant Abbott knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Louisiana, for TriCor.

242. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of Louisiana;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

243. The amounts of the false or fraudulent claims to the State of Louisiana were material.

244. Plaintiff State of Louisiana, being unaware of the falsity of the claims caused to be submitted by the Defendant, and in reliance on the accuracy thereof paid and continues to pay for non-covered and non-reimbursable claims for TriCor.

COUNT ELEVEN

Violations of the Massachusetts False Claims Act

ALM GL ch. 12 §§5A, *et seq.*

245. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

246. This Count is brought by Plaintiff-Relator Bergman in the name of the Commonwealth of Massachusetts under the *qui tam* provisions of the Massachusetts False Claims Act, Massachusetts Gen. Laws c.12 §5(A).

247. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the Commonwealth of Massachusetts, including TriCor.

248. The Massachusetts False Claims Act, Mass. Gen. Laws Ann. chap. 2, §5(B)(1)-(3), provides in part, that any person who:

- knowingly presents, or causes to be presented, a false or fraudulent claim for payment;
- knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the Commonwealth or any political subdivision thereof;
- conspires to defraud the Commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;

shall liable to the Commonwealth or political subdivision for a civil penalty or not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the Commonwealth or political subdivision sustains because of the act of that person.

249. By virtue of the above-described acts, among others, Defendant Abbott knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the Commonwealth of Massachusetts, for TriCor.

250. Specifically, Defendant has:

- caused thousands of false claims to be presented to the Commonwealth of Massachusetts;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

251. The amounts of the false or fraudulent claims to the Commonwealth of Massachusetts were material.

252. Plaintiff Commonwealth of Massachusetts, being unaware of the falsity of the claims caused to be submitted by the Defendant and in reliance on the accuracy thereof, paid and continues to pay for non-covered and non-reimbursable claims for TriCor.

COUNT TWELVE

Violations of the Montana False Claims Act 2005

Mont. Code Anno., §§17-8-401, *et seq.*

253. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

254. This Count is brought by Plaintiff-Relator Bergman in the name of the State of Montana under the *qui tam* provisions of the Montana False Claims Act, 2005 Mont. Code, CH. 465, HB 146, *et seq.*

255. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals, including TriCor, in the State of Montana.

256. The Montana False Claims Act, Mont. Code Ann., 17-8-403 provides for liability for *inter alia* any person who engages in any or all of the following conduct:

- Knowingly presenting or causing to be presented to an officer or employee of the governmental entity a false claim for payment or approval;

- Knowingly making, using, or causing to be made or used a false record or statement to get a false claim paid or approved by the governmental entity;

- Conspiring to defraud the governmental entity by getting a false claim allowed or paid by the governmental entity; or

- as a beneficiary of an inadvertent submission of a false claim to the governmental entity, subsequently discovering the falsity of the claim and failing to disclose the false claim to the governmental entity within a reasonable time after discovery of the false claim.

257. By virtue of the above-described acts, among others, Defendant Abbott knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Montana, for TriCor.

258. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of Montana;

- knowingly made, used or caused to be made or used false records to get false claims paid;

- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,

- failed to disclose the existence of the false claims it has caused to be presented.

259. The amounts of the false or fraudulent claims Defendant caused to be made to the State of Montana were material.

260. Plaintiff State of Montana, being unaware of the falsity of the claims caused to be submitted by the Defendant and in reliance on the accuracy thereof paid and may continue to pay for non-covered and non-reimbursable claims for TriCor..

261. At all times relevant to the complaint, Abbott acted with the requisite knowledge.

262. By virtue of the above-described acts, among others, Defendant Abbott knowingly engaged in conspiracies to defraud the Government of Montana by getting a false claim allowed or paid by the government for TriCor.

263. As a direct and proximate consequence of Defendant Abbott's conspiratorial conduct, the State of Montana has suffered significant, material financial damages in an amount to be proved at trial.

264. The State of Montana would not have suffered these devastating losses had the truth about Defendant's marketing plan been known.

COUNT THIRTEEN

Violations of the Tennessee Medicaid False Claims Act
Tenn. Code Ann. §§71-5-181, *et seq.*

265. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

266. This Count is brought by Plaintiff-Relator Bergman in the name of the State of Tennessee under the *qui tam* provisions of the Tennessee Medicaid False Claims Act, Tenn. Stat. §§ 75- I-181 *et seq.*

267. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Tennessee, including TriCor.

268. By virtue of the above-described acts, among others, Defendant Abbott knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Tennessee, for TriCor.

269. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of Tennessee;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

270. The amounts of the false or fraudulent claims to the State of Tennessee were material.

271. Plaintiff State of Tennessee, being unaware of the falsity of the claims and/or statements caused to be made by the Defendant, and in reliance on the accuracy thereof paid and may continue to pay for non-covered and non-reimbursable claims for TriCor.

COUNT FOURTEEN

Violations of the Tennessee False Claims Act

Tenn. Code Ann. §§4-18-101, *et seq.*

272. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

273. This is a qui tam action brought by Plaintiff Bergman on behalf of the State of Tennessee to recover treble damages, civil penalties and the cost of the civil action under the *qui tam* provisions of the Tennessee False Claims AAA, Tenn. Code Ann. § 4-18-101 *et seq.*

274. Tenn. Code Ann. §4-18-103, titled "Liability for violations," provides:

(a) Any person who commits any of the following acts shall be liable to the state or to the political subdivision for three (3) times the amount of damages which the state or the political subdivision sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state or to the political subdivision for the costs of a civil action brought to recover any of those penalties or damages, and shall be liable to the state or political subdivision for a civil penalty of not less than two thousand five hundred dollars ($2500) and not more than ten thousand dollars ($10,000) for each false claim:

- Knowingly presents or causes to be presented to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval;

- Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;

- Conspires to defraud the state or any political, subdivision by getting a false

claim allowed or paid by the state or by any political subdivision;

- Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

275. Defendant violated § 4-18-103(a)(1), (2), and (3) and knowingly presented or caused to be presented thousands of false claims from at least 2000 to the present by their violation of state and federal laws, including the Anti-Kickback Statute, as described herein.

276. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of Tennessee;

- knowingly made, used or caused to be made or used false records to get false claims paid;

- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and
- failed to disclose the existence of the Use claims it has caused to be presented.

277. The State of Tennessee, by and through Tennessee-funded health plans, and unaware of Defendant's illegal practices, paid the claims submitted by health care providers and third party payors in connection therewith.

278. Had the State of Tennessee known that Defendant violated the federal and state laws cited herein, it would not have paid the claims submitted by health care providers in connection with Defendant's fraudulent and illegal practices.

279. As a result of Defendant's violations of Tenn. Code Ann. §§4-18-103, the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive on interest.

280. Bergman is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Tenn. Code Ann. §§4-18-103 on behalf of herself and the State of Tennessee.

COUNT FIFTEEN

Violations of the Texas Medicaid Fraud Prevention Act

Tex. Hum. Res. Code, §§36.001, *et seq.*

281. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

282. This Count is brought by Plaintiff-Relator Bergman in the name of the State of Texas under the *qui tam* provisions of the Texas Medicaid Fraud Prevention Act, Tx. Human Resources Code, Ch. 36, §36.101 *et seq.*

283. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Texas, including TriCor.

284. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of Texas;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

285. By virtue of the above-described acts, among others, Defendant Abbott knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Texas for TriCor.

286. The amounts of the false or fraudulent claims to the State of Texas were material.

287. Plaintiff State of Texas, being unaware of the falsity of the claims caused to be submitted by the Defendant, and in reliance on the accuracy thereof paid and continues to pay for non-covered and non-reimbursable claims for TriCor..

COUNT SIXTEEN

Violations of the Virginia Fraud Against Taxpayers Act
Va. Code Ann. §§ 8.01-216.1, *et seq.*

288. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

289. This Count is brought by Plaintiff-Relator Bergman in the name of the Commonwealth of Virginia under the *qui tam* provisions of the Virginia Fraud Against Taxpayers Act, Va. Stat. Ch. 842, Article 19.1, § 8.01- 216.1 *et seq.*

290. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the Commonwealth of Virginia, including TriCor.

291. By virtue of the above-described acts, among others, Defendant Abbott knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the Commonwealth of Virginia, for TriCor.

292. Specifically, Defendant has:

- caused thousands of false claims to be presented to the Commonwealth of Virginia;

- knowingly made, used or caused to be made or used false records to get false claims paid;

- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and.

- failed to disclose the existence of the false claims it has caused to be presented.

293. The amounts of the false or fraudulent claims to the Commonwealth of Virginia were material.

294. Plaintiff Commonwealth of Virginia, being unaware of the falsity of the claims caused to he submitted by the Defendant, and in reliance on the accuracy thereof paid and continues to pay for non-covered and non-reimbursable claims for TriCor.

COUNT SEVENTEEN

Violations of the Indiana False Claims and Whistleblower Protection Act
Burns Ind. Code Ann. §§5-11-5.5. *et seq.*

295. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

296. This Count is brought by Plaintiff-Relator Bergman in the name of the State of Indiana under the qui *tam* provisions of IC 541-5.5-4, for the Defendant Abbott's violations of IC 5-11-5.5-2.

297. Defendant Abbott, al all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Indiana, including TriCor.

298. The Indiana False Claims and Whistleblower Act, Ind. Code § 5-11-5.5- 2(b) (2008), specifically provides that by engaging in certain acts a person commits

ar unlawful act and shall be liable to the state for civil penalties of at least $5,000 and for up to three times the amount of damages that the state sustains because of the act of that person, including:

(1) Presents a false claim to the state for payment or approval; or

(2) making or using a false record or statement to obtain payment or approval of a false claim from the state: or

(3) conspiring with another person to perform an act described above; or

(4) Causing or inducing another person to perform an act described above.

299. Through the acts described above and otherwise, Defendant Abbott knowingly caused to be presented for payment and approval to the Indiana Medicaid program, possibly continues to cause to be presented, directly or indirectly, to officers, employees or agents of the State of Indiana, false and fraudulent claims in order to induce Medicaid reimbursement for TriCor, and Defendant Abbott's other drugs, that were not eligible for any such reimbursement.

300. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of Indiana;
- knowingly made, used or caused to be made or used false records to get false claims paid:
- conspired to defraud the state by getting false and fraudulent claims allowed or paid: and,
- failed to disclose the existence of the false claims it has caused to be presented.

301. As a result, Plaintiff Indiana reimbursed Medicare and Medicaid participating providers for ineligible claims of TriCor, resulting in material financial losses to the State of Indiana.

302. Plaintiff State of Indiana, unaware of the falsity of the claims caused to be presented by Defendant Abbott, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for TriCor that would not have been paid or approved in any part if the truth were known.

303. By reason of Defendant Abbott's wrongful conduct, Indiana has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the State's false claims act in an amount to be determined at trial, plus civil penalties for each such false statement caused to be made or used by Abbott.

COUNT EIGHTEEN

Violations of the Nevada False Claims Act

Submission of False Claims to State or Local Government
Nev. Rev. Stat. Ann. §§357.010, *et seq.*

304. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

305. This Count is brought by Plaintiff-Relator Bergman in the name of the State of Nevada under the *qui tam* provisions of Nevada Rev. Stat. §357.010 *et seq.*, "Submission of False Claims to State or Local Government."

306. Defendant Abbott, at all times relevant to this action, sold and continue to sell pharmaceuticals in the State of Nevada, including TriCor.

307. Through the acts described above and otherwise, Defendant Abbott knowingly caused to be presented for payment and approval to the Nevada Medicaid program, possibly continues to cause to be presented, directly or indirectly, to officers, employees or agents of

the State of Nevada, false and fraudulent claims in order to induce Medicaid reimbursement for TriCor.

308. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of Nevada;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

309. At all times relevant and material to this Complaint, Defendant Abbott knowingly caused false claims for payment or approval for TriCor to be presented to officers and employees of the federal and state governments. As a result, the federal and state governments reimbursed Medicare and Medicaid provider pharmacies for ineligible claims for TriCor, resulting in great financial loss to the Nevada government.

310. By virtue of the above-described acts, among others, Defendant Abbott knowingly caused to be made or used and continues to cause to be made or used false or fraudulent statements to get claims allowed or paid for Tricor by the State of Nevada.

311. The amounts of the false or fraudulent claims and statements caused to be made by Abbott to the State of Nevada were material.

312. Plaintiff State of Nevada, being unaware of the falsity of the claims and/or statements caused to be made or used by Defendant, and in reliance on the accuracy thereof paid and continues to pay for non-covered and non-reimbursable claims for TriCor.

COUNT NINETEEN

Violations of the New Hampshire False Claims Act
§§167:61-b, *et seq.*

313. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

314. This Count is brought by Plaintiff-Relator Bergman in the name of the State of New Hampshire under the *qui tam* provisions of New Hampshire False Claims Act, 167:61-b *et seq.*

315. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of New Hampshire.

316. Through the acts described above and otherwise, Defendant Abbott knowingly caused to be presented for payment and approval to the New Hampshire Medicaid and Medicare programs, and continues to cause to be presented, false and fraudulent claims, directly or indirectly, to officers, employees or agents of the State of New Hampshire, to induce Medicaid and/or Medicare reimbursement for claims for TriCor that were not and are not eligible for any such reimbursement.

317. Through the acts described above and otherwise, Defendant Abbott knowingly caused to be made or used, and continues to cause to be made or used, false and fraudulent records and/or statements, in order to get claims for TriCor allowed or paid by Medicaid and/or Medicare, that were not eligible for any such reimbursement.

318. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of New Hampshire;

- knowingly made, used or caused to be made or used false records to get false claims paid;

- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,

- failed to disclose the existence of the false claims it has caused to be presented.

319. The amounts of the false or fraudulent claims to the State of New Hampshire were material.

320. Plaintiff State of New Hampshire, unaware of the falsity of the claims presented or caused to be presented by Defendant Abbott, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Defendant Abbott's drugs that would not have been paid or approved in any part if the truth were known.

321. By reason of Defendant Abbott's wrongful conduct, New Hampshire has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus the maximum penalties for each such false statement caused to be made or used by Defendant Abbott and each such false claim caused to be submitted by Defendant Abbott.

COUNT TWENTY

Violations of the New Mexico False Claims Act
N.M. Stat ANN. §§27-14-1 *et seq.*

322. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

323. This Count is brought by Plaintiff-Relator Bergman in the name of the State of New Mexico under the *qui tam* provisions of the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §27-14-1 *et seq.*

324. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of New Mexico, including TriCor.

325. Through the acts described above and otherwise, Defendant Abbott knowingly caused to be presented for payment and approval to the New Mexico Medicaid and/or Medicare programs, and continues to cause to be presented, false and fraudulent claims directly or indirectly, to officers, employees or agents of the State of New Mexico, in order to induce Medicaid and/or Medicare reimbursement for claims for TriCor that were not eligible for any such reimbursement.

326. Through the acts described above and otherwise, Defendant Abbott knowingly caused to be made or used, and continues to cause to be made or used, false and fraudulent records and/or statements, in order to get claims for TriCor allowed or paid by Medicaid and Medicare that were not eligible for any such reimbursement.

327. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of Nevada;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

328. The amounts of the false or fraudulent claims caused to be made to the State of New Mexico were material.

329. Plaintiff State of New Mexico, unaware of the falsity of the claims presented or caused to be presented by Defendant Abbott, and in reliance on the accuracy thereof,

have paid and approved, and continue to pay and approve, claims for TriCor that would not have been paid or approved in any part if the truth were known.

330. By reason of Defendant Abbott's wrongful conduct, New Mexico has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus the maximum civil penalty allowed under the state law for each such false claim caused to be submitted by Defendant Abbott and each such false statement caused to be made or used by Defendant Abbott.

COUNT TWENTY-ONE

Violations of the New Mexico Fraud Against Taxpayers Act
N.M. Stat. §§44-9-1 *et seq.*

331. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

332. This is a *qui tam* action brought by Plaintiff Bergman on behalf of the State of New Mexico to recover treble damages, civil penalties and the cost of the civil action under the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §44-9-1 *et seq*. N.M. Stat. Ann. § 44-9-3 (A) of the New Mexico Fraud Against Taxpayers Act provides that a person shall not:

(1) knowingly present, or cause to be presented, to an employee, officer or agent of the state or to a contractor, grantee or other recipient of state funds a false or fraudulent claim for payment or approval;

(2) knowingly make or use, or cause to be made or used, a false record or statement to obtain approval or payment on a false or fraudulent claim;

(3) conspire to defraud the state by obtaining approval or payment on a false claim;

(4) as a beneficiary of an inadvertent submission of a false claim and having subsequently discovered the falsity of the claim, fail to disclose the false claim to the state agency within a reasonable time after discovery.

333. Pursuant to N.M. Stat. Ann. § 44-9-3(B) of the New Mexico Fraud Against Taxpayers Act, proof of specific intent is not required for a violation of subsection A of Section 3.

334. Defendant at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of New Mexico.

335. By virtue of illicit illegal conduct and the other misconduct alleged herein, including causing the submissions of non-reimbursable claims for prescription drugs described above and using or causing to be used false or fraudulent records to accomplish this purpose, Defendant violated N.M. Stat. Ann. § 44-9-3(A) of the New Mexico Fraud Against Taxpayers Act with the requisite intent.

336. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of New Mexico;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

337. For example, claims for reimbursement for off-label prescriptions of Abbott's drug TriCor prescribed to government-funded health care program beneficiaries for non-medically accepted indications would not have been submitted to and paid the State of New Mexico but for the illegal practices of Defendant described in this Amended Complaint.

338. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

339. By reason of these improper payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

340. Defendant did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

341. Plaintiff is private persons with direct and independent knowledge of the allegations in this Complaint, who have brought this action pursuant to N.M. Stat. Ann. § 44-9-S of the New Mexico Fraud Against Taxpayers Act on behalf of herself and the State of New Mexico.

COUNT TWENTY-TWO

Violations of the Michigan Medicaid False Claims Act

MCLS §§400.601, *et seq.*

342. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

343. This Count is brought by Plaintiff-Relator Bergman in the name of the State of Michigan under the *qui tam* provisions of the Michigan False Claims Act, M.C.L.A. 400.601 *et seq.*

344. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Michigan, including TriCor.

345. Through the acts described above and otherwise, Defendant Abbott knowingly caused to be presented for payment and approval to the Michigan Medicaid and/or Medicare programs, and continues to cause to be presented, false and fraudulent claims, directly or indirectly, to officers, employees or agents of the State of Michigan, in order to induce Medicaid to reimburse Medicaid participating pharmaceutical providers for TriCor when those claims were not and are not eligible for any such reimbursement.

346. Through the acts described above and otherwise, Defendant Abbott knowingly caused to be made or used, and continues to cause to be used or made, false and fraudulent records and/or statements, in order to get claims for TriCor allowed or paid by Medicaid that were not eligible for any such reimbursement.

347. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of Michigan;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

348. The amounts of the false or fraudulent claims caused to be made to the State of Michigan were material.

349. Plaintiff State of Michigan, unaware of the falsity of the claims caused to be presented by Defendant Abbott, and in reliance on the accuracy thereof, have paid and

approved, and continue to pay and approve, claims for TriCor that would not have been paid or approved in any part if the truth were known.

350. By reason of Defendant Abbott's wrongful conduct, Michigan has suffered substantial financial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus the maximum allowable civil penalties for each such false statement caused to made or used by Defendant Abbott and each such false claim caused to be made by Defendant Abbott.

COUNT TWENTY-THREE

Violations of Michigan Public Acts, 1977 PA 72, as amended by 1984 PA 333 as amended by 2005 PA 337, as amended by 2008 PA 421

351. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

352. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act brought by Plaintiff Bergman on behalf of herself and the State of Michigan.

353. By virtue of the acts described above, Defendant has violated the Michigan Medicaid False Claims Act.

354. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of Michigan;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

355. For example, prescriptions for the purposes for off-label and non-medically accepted uses would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendant. As a result of this illegal scheme, these claims were improper in whole pursuant to the State of Michigan's False Medicaid Claims Act.

356. By virtue of the acts described above, Abbott knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

357. Each prescription that was written as a result of Defendant's illegal marketing practices represents a false or fraudulent record or statement. Each claim for reimbursement for such off-label prescriptions submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

358. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Abbott's conduct. The false claims were presented by many separate entities, and over many years.

359. The Michigan State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Abbott, paid and continues to pay the claims that would not be paid but for Abbott's false and illegal off-label marketing scheme.

360. By reason of Abbott's acts, the Michigan State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

361. The State of Michigan is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Abbott.

362. Defendant did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

363. Plaintiff is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Michigan's False Claims Act on behalf of herself and the State of Michigan.

COUNT TWENTY-FOUR

Violations of the New York False Claims Act

NY CLS St Fin. §§187 *et seq.*

364. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

365. This Count is brought by Plaintiff-Relator Bergman in the name of the State of New York under the *qui tam* provisions of the New York False Claims Act, N.Y. St. Fin. Law, §187 *et seq.*

366. Defendant Abbott at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of New York, including TriCor.

367. The New York False Claims Act, State Fin. Law § 189 specifically provides, in part, that a person commits an unlawful act if the person:

(a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or local government;

(c) conspires to defraud the state or a local government by getting a false or fraudulent claim allowed or paid.

368. Through the acts described above and otherwise, Defendant Abbott knowingly caused to be presented for payment and approval to the New York Medicaid and/or Medicare programs, and continues to cause to be presented, false and fraudulent claims, directly or indirectly, to officers, employees or agents of the State of New York, in order to induce Medicaid and or Medicare to reimburse Medicaid or Medicare participating pharmaceutical providers for TriCor when those claims were not and are not eligible for any such reimbursement.

369. Through the acts described above and otherwise, Defendant Abbott knowingly caused to be made or used, and continues to cause to be used or made, false and fraudulent records and/or statements, in order to get claims for TriCor allowed or paid by Medicaid and/or Medicare that were not eligible for any such reimbursement.

370. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of New York;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

371. The amounts of the false or fraudulent claims to the State of New York were material.

372. Plaintiff State of New York, unaware of the falsity of the claims caused to be presented by Defendant Abbott, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for TriCor that would not have been paid or approved in any part if the truth were known.

373. By reason of Defendant Abbott's wrongful conduct, New York has suffered substantial financial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus the maximum allowable civil penalties for each such false statement caused to made or used by Defendant Abbott and each such false claim caused to be made by Defendant Abbott.

COUNT TWENTY-FIVE

Violations of the Oklahoma Medicaid False Claims Act
63 Okla. Stat. §§5053, *et seq.*

374. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

375. This is a *qui tam* action brought by brought by Bergman and the State of Oklahoma to recover treble damages, civil penalties and the cost of this action, under the Oklahoma Medicaid False Claims Act, 63 Okla. Stat. § 5053, *et. seq.*

376. Defendant, from at least 2000 to the present, has engaged in a continuous practice of using and concealing unlawful marketing practices to promote the off-label and medically unnecessary use of TriCor, with the result that it has: (a) knowingly presented and caused to be presented, to an officer and employee of the State of Oklahoma, false and fraudulent claims for payment and approval; and (b) have knowingly made, used, and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the State of Oklahoma.

377. The Oklahoma Medicaid False Claims Act, 63 Okla. Stat. § 5053.1 (E), specifically provides in part:

i. Any person who:

- (1) knowingly presenting or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;

- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the state; and,

- (3) conspires to defraud the state by getting a false claim allowed or paid by the governmental entity.

is liable to the State of Oklahoma for a civil penalty of not less than $ 5000.00 and not more than $10,000.00, ... plus three times the amount of damages which the state sustains because of the act of that person.

378. Defendant knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the Oklahoma Medicaid program, claims which failed to disclose the material violations of the Oklahoma Medicaid False Claims Act.

379. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of Oklahoma;

- knowingly made, used or caused to be made or used false records to get false claims paid;

- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,

- failed to disclose the existence of the false claims it has caused to be presented.

380. For example, prescriptions for the purposes of off-label and non-medically accepted uses would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendant. As a result of this illegal scheme, these claims were improper in whole pursuant to the State of Oklahoma State False Medicaid Claims Act.

381. By virtue of the acts described above, Abbott knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

382. Each prescription that was written as a result of Defendant's illegal marketing scheme represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions for non-medically accepted uses submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

383. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Abbott's conduct. The false claims were presented by many separate entities, and over many years.

384. The Oklahoma State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Abbott, paid and continues to pay the claims that would not be paid but for Abbott's false and illegal off-label marketing practices.

385. For reason of Abbott's acts, the Oklahoma State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

386. Oklahoma is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Abbott.

387. Defendant did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

388. Relator is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Oklahoma False Medicaid Claims Act on behalf of herself and the State of Oklahoma.

COUNT TWENTY-SIX

Violations of the Wisconsin False Claims for Medical Assistance Act
WIS. STAT. §§20.931, *et seq.*

389. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

390. This is a *qui tam* action brought by brought by Bergman and the State of Wisconsin to recover treble damages, civil penalties and the cost of this action, under the Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § 20.931, *et, seq.*

391. Defendant, from at least 2000 to the present, have engaged in a continuous practice of using and concealing unlawful marketing practices to promote the off-label use of TriCor, with the result that they have: (a) knowingly presented and caused to be presented, to an officer and employee of the State of Wisconsin, false and fraudulent claims for payment and approval; and (b) have knowingly made, used, and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the State of Wisconsin.

392. The Wisconsin False Claims for Medical Assistance Act, WIS. STAT. §20.931(2), specifically provides in part:

> (1) Except as provided in sub. (3), any person who does any of the following is liable to this state for 3 times the amount of the damages sustained by this state because of the actions of the person, and shall forfeit not less than $5,000 nor more than $10,000 for each violation.
>
> (2) Knowingly presents or causes to be presented to any officer, employee, or agent of this state a false claim for medical assistance.
>
> (3) Knowingly makes, uses, or causes to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance.
>
> (4) Conspires to defraud this state by obtaining allowance or payment of a false claim for medical assistance, or by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance program.

393. Defendant knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the Wisconsin Medicaid program, claims which failed to disclose the material violations of the Wisconsin False Claims for Medical Assistance Act.

394. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of Wisconsin;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,

- failed to disclose the existence of the false claims it has caused to be presented.

395. For example, prescriptions for the purposes of off-label and non-medically accepted uses would not have been presented and paid but for the illegal incentives and unlawful promotional activities made by Defendant. As a result of this illegal scheme, these claims were improper in whole pursuant to the State of Wisconsin State False Medicaid Claims Act.

396. By virtue of the acts described above, Abbott knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

397. Each prescription that was written as a result of Defendant's illegal marketing practices represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions for off-label and non-medically accepted uses submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

398. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Abbott's conduct. The false claims were presented by many separate entities, and over many years.

399. The Wisconsin State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Abbott, paid and continues to pay the claims that would not be paid but for Abbott's false and illegal off-label marketing scheme.

400. By reason of Abbott's acts, the Wisconsin State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

401. Wisconsin is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Abbott.

402. Defendant did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

403. Relator is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the Wisconsin False Claims for Medical Assistance Act on behalf of herself and the State of Wisconsin.

COUNT TWENTY-SEVEN

Violations of the Rhode Island State False Claims Act
R.I. Gen. Laws §§9-1.1-1, *et seq.*

404. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

405. This is a *qui tam* action brought by brought by Bergman and the State of Rhode Island to recover treble damages, civil penalties and the cost of this action, under the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1, *et. seq.*

406. Defendant, from at least 2000 to the present, have engaged in a continuous practice of using and concealing unlawful marketing practices to promote the off-label use of TriCor, with the result that they have: (a) knowingly presented and caused to be presented, to an officer and employee of the State of Rhode Island, false and fraudulent claims for payment and approval; and (b) have knowingly made, used, and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the State of Rhode Island.

407. The Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-3(a), specifically provides in part:

> (a) Any person who:
>
> (1) Knowingly presents, or causes to be presented, to an officer or employee of the state or a member of the guard a false or fraudulent claim for payment or approval:
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
>
> (3) Conspires to defraud the state by getting a false or fraudulent claim allowed or paid; ... is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person. A person violating this subsection (a) shall also be liable to the state for the costs of a civil action brought to recover any such penalty or damages.

408. Defendant knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the Rhode Island Medicaid program, claims which failed to disclose the material violations of the Rhode Island False Claims Act.

409. Defendant knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the Rhode Island Medicaid program, claims which failed to disclose the material violations of the Rhode Island False Claims Act.

410. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of Rhode Island;

- knowingly made, used or caused to be made or used false records to get false claims paid;

- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,

- failed to disclose the existence of the false claims it has caused to be presented.

411. For example, prescriptions for the purposes of off-label and non-medically accepted uses would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendant. As a result of this illegal scheme, these claims were improper in whole pursuant to the State of Rhode Island False Claims Act.

412. By virtue of the acts described above, Abbott knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

413. Each prescription that was written as a result of Defendant's illegal marketing practices represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions for non-medically accepted uses submitted to a State-funded health insurance program represents a false or fraudulent claim in payment.

414. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Abbott's conduct. The false claims were presented by many separate entities, and over many years.

415. The Rhode Island State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Abbott, paid and continues to pay the claims that would not be paid but for Abbott's false and illegal off-label marketing scheme.

416. By reason of Abbott's acts, the Rhode Island State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

417. Rhode Island is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Abbott.

418. Defendant did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

419. Relators are private persons with direct and independent knowledge of the allegations in this Complaint, who have brought this action pursuant to the Rhode Island Fa se Claims Act on behalf of herself and the State of Rhode Island.

COUNT TWENTY-EIGHT

Violations of the New Jersey False Claims Act
N.J. STAT. §§2A:32C-1

420. Paragraphs 1 through 160 are incorporated herein as though set forth fully.

421. This is a *qui tam* action brought by brought by Bergman and the State of New Jersey to recover treble damages civil penalties and the cost of this action, under the New Jersey False Claims Act.

422. Defendant, from at least 2000 to the present, has engaged in a continuous practice of using and concealing unlawful marketing practices to promote the off-label and medically unnecessary use of TriCor, with the result that they have: (a) knowingly presented and caused to be presented, to an officer and employee of the State of New Jersey, false and

fraudulent claims for payment and approval; and (b) have knowingly made, used, and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the State of New Jersey.

423. The New Jersey False Claim Act prohibits any person from:

(1) Knowingly presenting, or causing to be presented, to an officer or employee of the state or a member of the guard a false or fraudulent claim for payment or approval;

(2) Knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;

(3) Conspiring to defraud the state by getting a false or fraudulent claim allowed or paid.

424. Defendant knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the New Jersey Medicaid program, claims which failed to disclose the material violations of the New Jersey False Claims Act.

425. Defendant knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the New Jersey Medicaid program, claims which failed to disclose the material violations of the New Jersey False Claims Act.

426. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of New Jersey;
- knowingly made, used or caused to be made or used false records to get false claims paid;
- conspired to defraud the state by getting false and fraudulent claims

allowed or paid; and,

- failed to disclose the existence of the false claims it has caused to be presented.

427. For example, prescriptions for the purposes of off-label and non-medically accepted uses would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendant, As a result of this illegal scheme, these claims were improper in whole pursuant to the State of New Jersey False Claims Act.

428. By virtue of the acts described above, Abbott knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

429. Each prescription that was written as a result of Defendant's illegal marketing scheme represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions for off-label and non-medically accepted uses submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

430. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Abbott's conduct. The false claims were presented by many separate entities, and over many years.

431. The New Jersey State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Abbott, paid and continues to pay the claims that would not be paid but for Abbott's false and illegal off-label marketing practices.

432. By reason of Abbott's acts, the New Jersey Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

433. New Jersey is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Abbott.

434. Defendant did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

435. Relator is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to the New Jersey False Claims Act on behalf of herself and the State of New Jersey.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff-Relator Amy Bergman, on behalf of herself, the United States of America and the States, demands and prays that judgment be entered as follows against the Defendant Abbott under the Federal False Claims Act Counts and under the various state False Claims Act counts, exclusive of interest and costs, as follows:

(a) In favor of the United States against Defendant Abbott for treble the amount of damages caused to Government health Care Programs (Medicaid, Medicare, Medicare Part D, TRICARE and FEHBP) from Abbott's illegal marketing scheme for TriCor as alleged herein, plus the maximum civil penalties of $11,000 (plus interest) for each false claim caused to be submitted, for each false record submitted or caused to be submitted;

(b) In favor of the United States against the Defendant Abbott for disgorgement of the profits earned by Defendant Abbott as a result of its illegal scheme;

(c) In favor of Plaintiff-Relator Bergman for the maximum amount allowed pursuant to 31 U.S.C. §3730(d) to include reasonable expenses, attorneys fees and costs incurred by Plaintiff-Relator Bergman;

(d) For all costs in bringing and prosecuting this action;

(e) In favor of the Plaintiff-Relator Bergman and the United States for such other relief as this Court deems just and equitable;

(f) In favor of the Plaintiff-Relator Bergman and the named State Plaintiffs against Defendant Abbott in an amount equal to three times the amount of damages that the named Plaintiff States have sustained as a result of the Defendant's actions, as well as the statutory maximum penalty against the Defendant Abbott for each violation of each State's FCA;

(g) In favor of Plaintiff-Relator Bergman for the maximum amount allowed as Relator's share pursuant to the Plaintiff State FCAs;

(h) In favor of Plaintiff-Relator Bergman for all costs and expenses associated with the supplemental claims of the plaintiff States, including attorney's fees and costs;

(i) In favor of the plaintiff States and Plaintiff-Relator Bergman for all such other relief as the Court deems just and proper; and,

(k) Such other relief as this Court deems just and appropriate.

REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38, Federal Rules of Civil Procedure, Plaintiff-Relator Amy Bergman hereby demands trial by jury.

DATED: January 4, 2012

Respectfully submitted,

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